MARK KADZIELSKI (BAR NO. 73376)
ROBERT M. DAWSON (BAR NO. 81790)
FULBRIGHT & JAWORSKI L.L.P.
555 South Flower Street, Forty-First Floor
Los Angeles, CA 90071
Telephone: (213) 892-9200
Facsimile: (213) 892-9494
Email: rmdawson@fulbright.com
mkadzielski@fulbright.com

Of Counsel:
FREDERICK R. ROBINSON (Pro Hac Vice Pending)
LORI-ANN BELLAN (Pro Hac Vice Pending)
FULBRIGHT & JAWORSKI L.L.P.
801 Pennsylvania Ave., N.W.
Washington, DC 20004
Telephone: (212) 662-0200
Facsimile: (212) 662-4643
Email: frobinson@fulbright.com
lbellan@fulbright.com

Attorneys for Plaintiff
GORDIAN MEDICAL, INC.

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

CV10-3933 CBM (FFMx)

GORDIAN MEDICAL, INC., Plaintiff, v. KATHLEEN SEBELIUS, Secretary of Department of Health and Human Services, Defendant.	Civil Action No. **COMPLAINT**

1. This is an action for judicial review of a final decision by the Secretary of the United States Department of Health and Human Services ("HHS"), through the Medicare Appeals Council ("MAC"), Docket Number M-10-498, to deny Plaintiff's

claims for Medicare reimbursement for medically necessary products provided to Medicare beneficiaries.

2. Plaintiff has exhausted its administrative remedies and is seeking review of claims for non-bordered composite dressings that were furnished to beneficiaries under Part B of the Medicare program. As a result of the illegal conduct by the Secretary's contractors, Plaintiff has been denied reimbursement on its claims for non-bordered composite dressings.

3. The total amount in controversy is $4,928,189.95.

4. Plaintiff is entitled to relief in this action pursuant to the Medicare Act, 42 U.S.C. § 405(g) and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 et. seq., including without limitation 5 U.S.C. §§ 704 and 706.

JURISDICTION AND VENUE

5. The Court has jurisdiction pursuant to 42 U.S.C. § 405(g). Plaintiff also is entitled to relief in this matter pursuant to the Administrative Procedure Act, 5 U.S.C. § 551 et. seq., including without limitation 5 U.S.C. § 704.

6. Venue is proper in this district pursuant to 42 U.S.C. § 405(g) and 28 U.S.C. § 1391(e).

PARTIES

7. Gordian Medical Inc., ("Gordian") is organized and exists under the laws of the State of Nevada ("Plaintiff"). Plaintiff has its principal place of business at 17595 Cartwright Road, Irvine, California 92614-5847. American Medical Technologies, Inc. ("AMT"), is a predecessor in interest to Gordian. At the time services were furnished to beneficiaries, AMT was a supplier in good standing with the Medicare program. AMT voluntarily surrendered its Medicare supplier number on August 8, 2008 and is no longer a Medicare supplier. Gordian has its own Medicare supplier number and is in good standing with the Medicare program.

8. Plaintiff furnishes Medicare beneficiaries with wound care supplies through a delivery/shipping service. Plaintiff furnishes composite dressings, which are generally

used as primary or secondary dressings on wounds, and other wound care supplies to Medicare beneficiaries throughout the country. Upon information and belief, Plaintiff is the largest supplier of non-bordered composite dressings in the country and receives the majority of reimbursements for this particular item from the Medicare program.

9. Defendant Kathleen Sebelius is the Secretary of the Department of Health and Human Services. In that capacity, she is responsible for the conduct and policies of HHS, including the conduct and policies of the Centers for Medicare and Medicaid Services ("CMS") and its contractors. She is sued in her official capacity.

THE MEDICARE PROGRAM

10. The Medicare Act was established under Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. §§ 1395 – 1395ggg, and provides payment for the provision of covered medical care services, equipment, and supplies to eligible aged and disabled persons.

11. Part B of the Medicare Act, 42 U.S.C. §§ 1395j – 1395w-4, provides supplementary medical insurance for covered medical services and covered medical supplies, including Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS"). Surgical dressings, including composite dressings, are among the medical supplies that may qualify for coverage under Medicare Part B and are items of DMEPOS. The Medicare statute and its implementing regulations establish conditions and limitations on the coverage of services, supplies and equipment, 42 U.S.C. §§ 1395k, 1395l, 1395x(s), as well as provide for exclusions from coverage. 42 U.S.C. § 1395y (a)(2)-(16); 42 C.F.R § 411.15(a)-(j). Medicare coverage is limited to services and equipment that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

13. The Secretary employs various mechanisms to explain coverage and exclusions from coverage. For example, a national coverage determination ("NCD") is "a determination by the Secretary with respect to whether or not a particular item or

service is covered nationally . . . but does not include a determination of what code, if any, is assigned to a particular item or service covered under this subchapter or a determination with respect to the amount of payment made for a particular item or service so covered." 42 U.S.C. § 1395ff(f)(1)(B). In addition, Medicare contractors may issue a "local coverage determination" ("LCD"), which is a "determination by a fiscal intermediary or a carrier under part A . . . or part B . . . respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis . . . ." 42 U.S.C. § 1395ff(f)(2)(B). Essentially, an LCD is a decision by a Medicare contractor regarding whether a particular item or service falling within the contractor's jurisdiction is covered as reasonable and medically necessary. A Policy Article is another mechanism used by Medicare contractors to inform providers about certain changes to coverage guidelines for Medicare covered items within their respective jurisdictions. According to CMS, an "LCD only contains reasonable and necessary language," http://www.cms.gov/DeterminationProcess/ 04_LCDs.asp, any "non-reasonable and necessary language a contractor wishes to communicate to providers must be done through an article." Id.

14. An aggrieved party can request review of an NCD or an LCD. An NCD can be reviewed by the Departmental Appeals Board ("DAB"), and an LCD may be reviewed by an Administrative Law Judge ("ALJ"). The final decisions of the DAB and the ALJ are subject to judicial review. 42 U.S.C. §§ 1395ff(f)(1) and (2); 42 C.F.R. Part 426, Subparts D and E. There is no such administrative review mechanism available for Policy Articles.

15. Claims for DMEPOS items and services are submitted to one of four Durable Medical Equipment Medicare Administrative Contractors, commonly referred to as "DME-MACs" (formerly known as Durable Medical Equipment Regional Carriers ("DMERCs")) that are agents of CMS. The geographic jurisdictions of the DME-MACs are fixed by CMS and whether a claim falls under their purview depends upon the residence of the Medicare beneficiary on whose behalf a claim for payment is

submitted. Pursuant to contracts between CMS and the individual DME-MACs, Medicare claims are processed by the following DME-MACs in their respective jurisdictions: (a) NHIC, Corp. - Jurisdiction A; (b) National Government Services/AdminaStar Federal - Jurisdiction B; (c) CIGNA Government Services - Jurisdiction C; and (d) Noridian Government Services - Jurisdiction D. The DME-MACs process claims and are not responsible for developing coverage guidelines or policies.

16. In addition to DME-MACs, during the relevant time period at issue, Durable Medical Equipment Program Safeguard Contractors ("DME PSCs") contracted with CMS and helped administer the Medicare program. DME PSCs were responsible for creating Medicare coverage guidelines, formulating LCDs (with CMS's approval), and conducting medical review/utilization review of claims within their respective jurisdictions. There were three DME PSCs during the relevant time period: (a) TriCenturion - Jurisdictions A and B, Dr. Paul J. Hughes, Medical Director; (b) TrustSolutions, L.L.C. - Jurisdiction C, Dr. Adrian M. Oleck, Medical Director; and (c) IntegriGuard, L.L.C. – Jurisdiction D, Dr. Mark D. Pilley, Medical Director.[1]

17. Medicare contractors, upon receipt and processing of a claim for payment, make an "initial determination," deciding whether the items or services that are the subject of the claim are covered, as well as the amount payable for such items or services. 42 U.S.C. § 1395ff(a)(1); 42 C.F.R § 405.920. The Medicare statute and implementing regulations provide an administrative appeal process for aggrieved parties who disagree with an initial determination. The following levels of review are available for claimants who are dissatisfied with any initial determination:

(a) First Level of Appeal - Redetermination by the contractor that processed the claim, (42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940);

[1] DME PSCs are no longer performing the above-described functions as Medicare contractors. Dr. Richard Whitten has replaced Dr. Pilley as the Medical Director in Jurisdiction D.

(b) Second Level of Appeal - Reconsideration by a Qualified Independent Contractor ("QIC"), (42 U.S.C. §§ 1395ff(b)(1)(A) and (c); 42 C.F.R. § 405.960);

(c) Third Level of Appeal – Review by an Administrative Law Judge in the Office of Medicare Hearings and Appeals, (42 U.S.C. §§ 1395ff(b)(1)(A), (E) and (d)(1); 42 C.F.R. § 405.1002);

(d) Fourth Level of Appeal - Review by the Medicare Appeals Council, (42 U.S.C. §§ 1395ff(d)(2); 42 C.F.R. § 405.1100); and

(e) Fifth Level of Appeal – Judicial review in Federal District Court, (42 U.S.C. §§ 1395ff(b)(1)(A), (E); 42 C.F.R. § 405.1136).

18. Pursuant to Title II, subtitle F of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 42 U.S.C. § 1320d-2, Congress required the Secretary to adopt and implement standards and requirements for coding systems to facilitate the electronic transmission of certain health information.

19. On August 17, 2000, CMS published regulations (45 C.F.R. § 162.1002) to implement the HIPAA requirement for standardized coding systems. It established the Healthcare Common Procedure Coding System ("HCPCS") Level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions that are not otherwise identified by HCPCS Level I, CPT codes. HCPCS is the means by which DMEPOS items and services are identified for Medicare billing, among other functions.

20. During the relevant time period, the Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") was a national entity that also provided services under contract to, and was an agent of, CMS.[2] The SADMERC HCPCS Unit offered guidance to manufacturers and suppliers on the proper use of the HCPCS. Additionally, the SADMERC performed a variety of national pricing functions for DMEPOS services, assisted CMS with the DMEPOS Fee Schedules, and analyzed

[2] The Pricing Data Analysis and Coding Contractor ("PDAC") replaced the SADMERC in August 2008 and generally performs the same functions under contract with CMS. For purposes of this lawsuit, we will continue to refer to the entity as the SADMERC since that was the name of the entity during the relevant time period.

DMEPOS fees to identify unreasonable or excessive reimbursement amounts. CMS instructed manufacturers and suppliers to contact the SADERC HCPCS Unit to obtain proper billing codes for DMEPOS items and determination of proper billing identification codes for new products or items.

21. Medicare payment for DMEPOS items and services is currently based on a fee schedule payment methodology, pursuant to section 1834 of the Act. 42 U.S.C. § 1395m. The payment for surgical dressings under Part B is 80 percent of the lesser of the actual charge for the item or the amount set by the fee schedule payment methodology. Id. Fee schedule payment amounts for DMEPOS are the same for all items included in a HCPCS code, varying only slightly by geographic area.

FACTUAL BACKGROUND

22. Plaintiff is a Medicare supplier of wound care supplies, including, but not limited to, non-bordered composite dressings, which generally are wound care dressings that do not contain a built-in adhesive border. Plaintiff primarily furnishes wound care supplies to residents of long term care facilities. Plaintiff files claims with several CMS authorized contractors for the processing and reimbursement of claims for supplies that are furnished to beneficiaries under Part B of the Medicare program.

23. The non-bordered composite dressings furnished by Plaintiff are manufactured by MPM Medical, Inc. ("MPM") and Medline Industries, Inc. ("Medline"). 24. MPM and Medline independently requested and received separate coding decisions from the SADMERC regarding the appropriate HCPCS codes to use for non-bordered composite dressings for purposes of Medicare billing, as required by CMS mandate.

25. The SADMERC determined that the non-bordered composite dressings manufactured by MPM and Medline met the description for non-bordered composite dressings as defined in the DMERC Medical Policy for Surgical Dressings, in December 2004 and April 2006, respectively. Accordingly, the SADMERC assigned the non-bordered composite dressings to the following HCPCS Codes: (a) A6200 for

Composite dressing, pad 16 sq. in. or less, without adhesive border; (b) A6201 for a Composite dressing, pad size more than 16 sq. in. or less than 48 sq. in., without adhesive border; and (c) A6202 for a Composite dressing, pad size more than 48 sq. in., without adhesive border.

26. Pursuant to the SADMERC's decisions, Plaintiff has submitted claims for non-bordered composite dressings for reimbursement under Medicare Part B with HCPCS codes A6200, A6201, and A6202.

27. Shortly after it began to submit claims under these HCPCS codes, the DME-MACs began denying large numbers of claims submitted by Plaintiff due to a purported lack of medical necessity. For example, between September 1, 2004 and August 1, 2005, thousands of Plaintiff's claims were denied based upon an alleged lack of medical necessity. Plaintiff appealed these determinations and the vast majority of these cases were overturned on appeal by Administrative Law Judges ("ALJs"). For example, Administrative Law Judge Alexander Weir III, of the Social Security Administration, has adjudicated 11,874 of Plaintiff's claims and three (3) overpayment cases containing multiple claims, and reversed the decisions of the DME-MACs in approximately 98% of the cases. The HHS Office of Medicare Hearings and Appeals has also adjudicated 26,373 of Plaintiff's claims with a 98% reversal rate.

28. During the relevant time period, the DME PSC Medical Directors provided testimony at these ALJ hearings through various means, including in-person and telephonic appearances and by letter. Their testimony regarding the medical necessity of Plaintiff's products was consistently rejected by the ALJs.

29. Upon information and belief, the DME PSC Medical Directors, faced with the prospect of continuing reversals in the administrative appeal process, decided collectively to devise a strategy that would allow them to deny Plaintiff's claims while shielding their decisions from any administrative review. This decision had several components including: (1) changing the definition of composite dressings; (2) invalidating HCPCS codes A6200, A6201, and A6202; and (3) denying reimbursement

for these claims under a technical classification and thereby refusing to grant an administrative remedy to suppliers whose claims for such codes have been denied.

30. First, the DME PSCs, without authority, purported to change the definition of "composite dressings." As discussed above, the DME PSCs were responsible, in part, for creating Medicare coverage guidelines and policies, but were not responsible for defining the products that qualify for HCPCS codes.

31. In September 2006, two contractors and agents of CMS, TriCenturion, the Region A/B DME PSC, and Palmetto GBA, a former DMERC, issued bulletins pursuant to which they purported to revise the definition of composite dressings. The change was stated to be effective for claims with dates of service on or after October 1, 2006. In March 2007, the other DME PSCs followed suit and notified the supplier community through a Policy Article about the alleged revisions to the definition of composite dressings, with a retroactive effective date of January 2007. As discussed above, CMS contractors use a Policy Article as a mechanism to inform the supplier community about certain changes to coverage guidelines for Medicare covered items within their respective jurisdictions. The revised definitions contained in the Policy Article required, for the very first time, that a composite dressing have a physical adhesive border.

32. Prior to January 2007, the term "composite dressings" was defined as follows by the DMERC Medical Policy for Surgical Dressings:

> Composite dressings (A6200-A6205) are products combining physically distinct components into a single dressing that provides multiple functions. These functions must include, but are not limited to: (a) a bacterial barrier, (b) an absorptive layer other than an alginate or other fiber gelling dressings, foam, hydrocolloid, or hydrogel, and (c) either a semi-adherent or non-adherent property over the wound site.

33. Effective January 2007, the DME PSC's Policy Article contained the following definition for composite dressings:

> Composite dressings (A6200-A6205) are products combining physically distinct components into a single dressing that provides multiple functions. These functions must include, but are not limited to: (a) a physical (not chemical) bacterial

> barrier that is present over the entire dressing pad and extends out into the adhesive border, (b) an absorptive layer other than an alginate or other fiber gelling dressing, foam, hydrocolloid, or hydrogel, and (c) either a semi-adherent or nonadherent property over the wound site.
>
> Codes for composite dressings without adhesive border (A6200, A6201, and A6202) are invalid for claim submission.

34. The second major way in which the DME PSCs have attempted to shield their decisions from administrative review was by unilaterally invalidating HCPCS codes A6200, A6201, and A6202.

35. Although the SADMERC had previously indicated that non-bordered composite dressings sold by Plaintiff were appropriately classified by HCPCS codes A6200, A6201, or A6202, the Policy Article at issue indicates that codes for composite dressings without adhesive border A6200, A6201, and A6202 would be invalid for claim submission.

36. In response to the announced invalidation of these codes, Plaintiff contacted the Coverage and Analysis Group ("CAG") within the Office of Clinical Standards and Quality of CMS. In turn, CAG requested that the Medical Directors of the DME PSCs at the time provide an explanation as to why the HCPCS codes were invalidated. The Medical Directors, who at the time included Drs. Paul Hughes, Mark Pilley and Adrian Oleck, responded to CAG that they had not invalidated the HCPCS codes or eliminated coverage of non-bordered composite dressings, but merely had decided that non-bordered dressings no longer met the definition of "composite dressings." In fact, the Medical Directors had changed the applicable definition and unilaterally invalidated HCPCS codes A6200, A6201, and A6202. They did so knowing that there were, and continue to be, no other products on the market that fit the revised definition of these codes.

37. During this time, Plaintiff made several telephone inquiries to the CMS HCPCS Unit, including the HCPCS Coordinator, who confirmed that HCPCS codes A6200, A6201, and A6202 were in fact still valid for claim submission.

38. During this time, there was an established procedure within CMS for revising HCPCS codes. According to CMS's Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures in place at the time, requests for coding revisions should have been made to CMS. See Exhibit 1. Anyone, including the DME-MACs, could have submitted a request for modifying the HCPCS Level II national code set. The procedures indicated that a request for coding revisions should be sent to the Center for Medicare Management within CMS recommending the modification of a code. There were three types of coding revisions to the HCPCS codes that could be requested, including, but not limited to, revising the language used to describe an existing code.

39. According to these procedures, when a recommendation for revisions to the HCPCS was received, it was to be reviewed at a regularly scheduled meeting of the CMS HCPCS Workgroup. The HCPCS Level II Coding Procedures indicated that the CMS Workgroup was an internal workgroup comprised of representatives of the major components of CMS, the Medicaid State agencies and the SADMERC. Importantly, according to CMS' HCPCS Level II Coding Procedures, the "CMS HCPCS Workgroup [was] responsible for making the final decisions pertaining to additions, deletions, and revisions to the HCPCS codes," not the DME PSCs. The CMS HCPCS Workgroup was to review all requests for coding changes and make final decisions regarding the annual update to the national codes. The SADMERC participated in this process by representing Medicare program operating needs with input from the four Medicare contractors that had responsibility for processing DMEPOS claims for the Medicare program.

40. The HCPCS Level II Coding Procedures also stated that the CMS Workgroup applied certain criteria to determine whether there was a demonstrated need for a new or modified code or the need to remove a code. According to those procedures, when an existing code adequately described the item in a coding request, then no new or modified code would be established. Notably, any existing code also described products with (a) functions similar to the item in the coding request and (b) no significant therapeutic distinctions from the item in the coding request. The

procedures further provided that when an existing code described products that were almost the same in function with only minor distinctions from the item in the coding request, the item in the coding request might be grouped with that code and the code descriptor modified to reflect the distinctions.

41. Upon information and belief, the DME PSCs did not submit to the CMS Workgroup a formal request to change the definition of HCPCS codes A6200, A6201, and A6202 prior to the DME PSCs' unilateral change in definition of such codes. In addition, the DME PSCs apparently did not adhere to the criteria outlined in the HCPCS Level II Coding Procedures.

42. The DME PSCs have acted in willful disregard of CMS procedures when they changed the definition of "composite dressings" and invalidated the applicable HCPCS codes.

43. Based upon the revised definition, if a composite dressing does not have an adhesive border, then it does not qualify as a "composite dressing" and will therefore, not be reimbursed under HCPCS codes A6200, A6201, or A6202.

44. There is no medical justification for the change in definition. The DME PSCs seem to suggest that a composite dressing must have an adhesive border in order to maintain a bacterial barrier. However, this reasoning is completely flawed in that the lack of a built-in adhesive border does not compromise the bacterial shield of a composite dressing. Plaintiff obtained several medical opinions from nationally respected wound care experts pointing out the flaw in this reasoning and provided such opinions to the CAG and the DME PSC Medical Directors for review. See Exhibit 2.

45. In contradiction to the position apparently adopted by the DME PSC Medical Directors, all of these clinical experts agreed that the bacterial shield of a composite dressing is not compromised by the lack of an adhesive border. In fact, all of these medical experts generally concluded that the adhesive borders are provided primarily as a means of convenience to minimize the need for other forms of securement during application of the dressing. According to the clinical experts, non-bordered composite

dressings generally contain an absorbent layer placed on a moisture barrier film backing. This layer is of equal or greater importance in maintaining the bacterial barrier as are the absorptive properties of the dressing in controlling exudate and reducing the climate for bacterial proliferation.

46. CAG ignored the expert medical opinions provided by Plaintiff.

47. The DME PSCs' unilateral decision to change the definition of composite dressings in spite of the expert medical opinions provided by Plaintiff and to invalidate the codes at issue bypassed both the SADMERC and the CMS HCPCS Workgroup and thus failed to ensure balanced, rationally-based decision making.

48. The DME PSCs were required to follow established CMS guidelines in order to revise and invalidate HCPCS codes A6200, A6201, and A6202.

49. After the Policy Article, which is not subject to administrative review, was issued and purportedly changed the definition of composite dressings, Plaintiff continued to submit claims for reimbursement under HCPCS codes A6200, A6201, and A6202.

50. Plaintiff has been denied reimbursement totaling $741,442 for the period October 1, 2006 through October 31, 2007. The number of claims denied during this time period is 1,714. In total, Plaintiff has been denied reimbursement totaling $4,928,189.95.

51. Beginning December 1, 2007, up until March 31, 2008, the Medicare contractors' processing of the Plaintiff's claims for non-bordered composite dressings had become chaotic among Jurisdictions:

- Jurisdiction A processed claims containing non-bordered composite dressings normally with no reimbursement determination distinction made among dressings.
- Jurisdiction B split the claims containing non-bordered composite dressings into the following two segments: (1) a segment with only non-bordered composite dressings; and (2) a segment containing all other items. The segment containing only the non-bordered composite dressings was denied using an "invalid HCPCS

code" explanation, indicating that there are no further appeal rights for the determination. The segment containing the remaining items were processed normally.

- Jurisdiction C summarily rejected any claim containing a non-bordered composite dressing. Jurisdiction C responded to each claim with an "invalid HCPCS code" explanation and completely denied the claim access into the processing system. Without even a rudimentary processing and reimbursement determination, there could be no administrative appeal because the claim was deemed not to exist.
- Jurisdiction D processed claims containing non-bordered composite dressings normally with no distinction made regarding reimbursement determinations among dressings.

52. Now, all Jurisdictions deny Plaintiff's claims for non-bordered composite dressings.

53. The third major way in which the DME PSCs attempted to shield their decisions from administrative review was to deny Plaintiff any administrative remedy to appeal its claims for non-bordered composite dressings.

54. As indicated above, Jurisdiction B denied Plaintiff's claims for non-bordered composite dressings containing HCPCS codes A6200, A6201, and A6202. Plaintiff's requests were denied with processing code MA130, indicating that such claims contained "incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable." Plaintiff filed requests for redetermination of the denied claims. Plaintiff's claims were again denied and Plaintiff was informed that no administrative appeal remedy was available. Jurisdiction C also failed to provide Plaintiff with an administrative appeal remedy because it denied Plaintiff's claims for non-bordered composite dressings access into the processing system.

55. On February 25, 2008, Plaintiff filed suit under 28 U.S.C. § 1331 against the Secretary in the United States District Court for the District of Columbia seeking judicial review of the issues described above (the "AMT Litigation").

56. The Secretary argued, in relevant part, that the Medicare statute, 42 U.S.C. §§ 405(h) and 1395ii, expressly barred federal question jurisdiction and required the Plaintiff to exhaust available administrative appeals remedies and obtain a final decision of the Secretary before filing suit in federal district court under 42 U.S.C. §§ 405(g) and 1395ff. In order to obtain administrative review of the issues presented by Plaintiff, the Secretary further argued that Plaintiff could file its claims using the alternative HCPCS codes for specialty absorptive dressings, (A6251, A6252, A6253), that are referenced in the September 2006 bulletin issued by TriCenturion and Palmetto GBA, discussed above. The Secretary took the position that Plaintiff's objections regarding the revised definition of "composite dressings" and the invalidation of HCPCS codes could be completely addressed within the Medicare administrative review mechanism. Plaintiff disagreed that these issues could be adequately addressed in the administrative review process, noting in particular that, pursuant to 42 C.F.R. § 405.926(c), disputes relating to the computation of payment amounts are not addressed in the administrative appeal process.

58. On February 25, 2009, the Court dismissed Plaintiff's lawsuit for lack of subject matter jurisdiction due to the Medicare statute's jurisdictional exclusivity and exhaustion requirements. According to the Court, Plaintiff could have "availed itself of the Medicare administrative review mechanism" using the Secretary's approach, described above. The Court further noted that "[i]f plaintiff were to appeal from an initial determination using the new billing codes . . . it would not be raising an 'issue regarding the computation of the payment amount.' Rather, plaintiff would be raising an issue regarding the approach the contractors used in invalidating the old codes and issuing the new ones."

59. Plaintiff thereafter availed itself of the administrative appeals process and sought administrative review of its claims for non-bordered composite dressings with the relevant contractors. Plaintiff re-filed certain claims using the alternative codes, as suggested by the Secretary and directed by the Court. Plaintiff also filed additional

claims using the original codes. Plaintiff's entire universe of claims for composite dressings are at various stages of administrative appeal.

60. The claims for non-bordered composite dressings that are the subject of the Secretary's final decision and that are the subject of this case were filed using the original codes for non-bordered composite dressings. Those claims were denied by Cigna Government Services ("Cigna"), a Medicare contractor. Cigna found that the claims were not covered pursuant to Policy Article A24114.

61. Plaintiff timely filed a request for reconsideration with the QIC. The QIC also denied Medicare coverage of the claims for non-bordered composite dressings. The Secretary argued in the AMT Litigation that the "QIC's 'panel' must have sufficient medical expertise and knowledge of the Medicare program, which will enable the QIC to review and address the conflicting medical opinions regarding the matters raised" by the Plaintiff. See Exhibit 3 (Def.'s Mem. In Supp. of Mo. To Dismiss at 29). Plaintiff, however, was not provided any such opportunity.

62. Plaintiff then filed a timely request for an ALJ hearing. The ALJ issued a decision on April 1, 2009 and concluded that the non-bordered composite dressings at issue were not covered by Medicare, in accordance with the "LCD Policy Article". The ALJ mistakenly characterized the March 2007 Policy Article as part of the LCD and noted that because Plaintiff did not follow the procedures for review of LCDs, the ALJ did not address the validity, reasonableness or enforceability of the LCD at issue. However, as discussed above, there are no administrative review procedures for Policy Articles.

63. The Plaintiff timely appealed the ALJ's decision to the MAC. In its request for review, the Plaintiff argued the following: (a) that the invalidated HCPCS codes (A6200-A6202) still exist and are, therefore, reimbursable; (b) that CMS erred in not using the HCPCS Level II Workgroup coding procedures to invalidate the codes; and (c) that CMS erred in allowing DME PSCs to issue a Policy Article invalidating these codes in March 2007.

64. On October 8, 2009, the MAC remanded the case to the ALJ based on the fact that the exhibit record appeared to be incomplete.

65. On December 31, 2009, the ALJ returned the record to the MAC indicating that that the record was in fact complete.

66. In a decision dated March 24, 2010, the MAC found that an "ALJ and the Council only have the authority to review appeals of 'initial determinations,' as that term is defined in 42 C.F.R. § 405.924. Actions that are not initial determinations include any issue for which CMS has sole responsibility; any issue regarding the computation of the payment amount of general applicability for which the CMS or the carrier has the sole responsibility, such as actions regarding the establishment of a fee schedule under 42 C.F.R. part 414; and, claims submissions that do not meet the requirements for a Medicare claim."

67. The MAC also stated that neither the ALJ nor the MAC has the authority to review the Healthcare Common Procedure Coding System or HCPCS codes, including the uniform national definitions of services, codes to represent services, and payment modifiers to the codes. The MAC further stated that it does not have the "authority to review the PSCs' invalidation of codes, or any CMS action or inaction with respect to coding issues." The MAC found that Plaintiff's claims for non-bordered composite dressings billed under HCPCS codes A6200, A6201, and A6202, are not Medicare covered items.

68. In this way, the MAC refused to review the issues that the Secretary assured the Court would be reviewed in the administrative appeal process in urging dismissal of the AMT Litigation.

69. Plaintiff's entire universe of claims have thus far been denied at every level of the appeals process. Since the MAC has decided that neither an ALJ nor the MAC have the authority to decide the issues presented by the Plaintiff's administrative appeals, further administrative review would be futile. Accordingly, the entire universe of claims are included in this request for judicial review.

COUNT I

(Invalidity of Agency Action Based on Failure to Act in Observance of Procedure Required By Law in Violation of the Medicare Act and the Administrative Procedure Act 42 U.S.C. § 405 (g); 5 U.S.C. §§ 706(2)(A), (D))

70. The allegations contained in paragraphs 1 - 69 above are realleged and incorporated by reference herein.

71. Defendants were not authorized under HCPCS Level II Coding Procedures to unilaterally invalidate or revise the definition of HCPCS codes for submission of claims under the Medicare program.

72. Defendant's invalidation of HCPCS codes is contrary to established CMS HCPCS Level II Coding Procedures, and is therefore unlawful pursuant to 5 U.S.C. §§ 706(2)(A), (D).

73. The DME PSCs failure to observe and comply with the Defendant's established HCPCS Level II Coding Procedures in order to invalidate and revise the definition of HCPCS codes A6200, A6201, A6202 constitutes invalid agency action based on failure to act in observance of procedure required by law, is a violation of the Medicare statute and regulations as well as the Administrative Procedure Act, 5 U.S.C. §§ 706(2)(A), (D). Plaintiff is therefore requesting this Court to conclude that Defendants' revision and invalidation of HCPCS codes is not authorized under CMS's established guidelines and an order preventing Defendants from further implementation of such revisions and invalidation of HCPCS codes A6200, A6201, and A6202.

COUNT II

(Invalidity of Agency Action In Violation of the Administrative Procedure Act Pursuant to 5 U.S.C. § 706)

75. The allegations contained in paragraphs 1 - 74 above are realleged and incorporated by reference herein.

76. Defendant's purported change in the definition of "composite dressings" without following established HCPCS Level II Coding Procedures is arbitrary and capricious agency action.

77. Defendant's subsequent invalidation of HCPCS codes A6200, A6201, and A6202 is contrary to established HCPCS Level II Coding Procedures and is therefore invalid agency action.

78. Defendant's establishment of new substantive standards of payment and eligibility for the provision of non-bordered composite dressings to Medicare beneficiaries without following CMS's HCPCS Level II Coding Procedures is arbitrary and capricious, an abuse of discretion and is therefore unlawful.

79. Defendant's denial of Plaintiff's claims for alleged technical reasons is arbitrary and capricious and an abuse of discretion.

80. Defendant's failure to provide an administrative remedy is without observance of procedure, is not in accordance with law and is therefore unlawful.

81. The Plaintiff has exhausted its administrative remedies to the extent possible. The MAC has ruled that neither the ALJ nor the MAC have the authority to review the issues presented by Plaintiff. Forcing the Plaintiff to avail itself of an administrative process that has no authority to review Plaintiff's issues is arbitrary and capricious and not in accordance with the law.

82. Defendant has intentionally acted in ways to arbitrarily deny Plaintiff's claims for non-bordered composite dressings without justification.

83. Plaintiff has no other adequate administrative or other remedies available to redress Defendant's repeated denial of Plaintiff's claims for non-bordered composite dressings. 5 U.S.C. § 704.

84. Plaintiffs are entitled to an order requiring CMS and its contractors to follow established CMS HCPCS Level II Coding Procedures to revise and invalidate a HCPCS code and payment on its denied claims as a result of this unlawful revision and invalidation.

COUNT III

(Arbitrary and Capricious Action In Violation of the Administrative Procedure Act Pursuant to 5 U.S.C. § 706)

85. The allegations contained in paragraphs 1-84 above are realleged and incorporated by reference herein.

86. In March 2007, Defendant's contractors retroactively applied the Policy Article regarding the purported revisions to the definition of composite dressings. Even if the Policy Article was a valid exercise of the Defendant's discretion, the retroactive application of such Policy Article is arbitrary and capricious and not in accordance with law in violation of the Administrative Procedure Act, 5 U.S.C. § 706.

87. As a result of Defendant's unlawful actions, Plaintiff has suffered and will continue to suffer irreparable injury.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff respectfully requests as relief in this action that the Court:

1. Enter an order declaring that Defendant's revision and invalidation of HCPCS codes A6200, A6201, and A6202 is not authorized under established HCPCS Level II Coding Procedures and is null and void and of no effect.

2. Order the Defendant to process and reimburse Plaintiff's claims for composite dressings that were denied for technical reasons at the appropriate fee

schedule amounts that were in effect at the time supplies were furnished to beneficiaries.

3. Enter an order preventing the Defendant from further implementation of such revisions and invalidation of HCPCS codes A6200, A6201, and A6202 without following CMS's established HCPCS Level II Coding Procedures.

4. Declare that the SADMERC definition of composite dressings that existed prior to September 2006 be followed by the Defendant.

5. Enjoin the Defendant from initiating overpayment demands based upon reimbursement resulting from claims containing HCPCS codes A6200, A6201, and A6202 that were processed and paid.

6. Award Plaintiff such other relief as the Court may deem just and proper.

Dated: May 25, 2010

MARK KADZIELSKI
ROBERT M. DAWSON
FULBRIGHT & JAWORSKI L.L.P.

Of Counsel
FREDERICK ROBINSON
LORI-ANN BELLAN
FULBRIGHT & JAWORSKI L.L.P.

By _____
ROBERT M. DAWSON
Attorneys for Plaintiff
GORDIAN MEDICAL, INC.

EXHIBIT 1

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODING PROCEDURES

This information provides a description of the procedures CMS follows in making coding decisions.

FOR FURTHER INFORMATION CONTACT:

Gloria Knight (410) 786-4598, Felicia Eggleston (410) 786-9287, Jennifer Carver (410) 786-6610, Trish Brooks (410) 786-4561, or Cindy Hake (410) 786-3404 for HCPCS level II coding issues.

A. HCPCS BACKGROUND INFORMATION

Each year, in the United States, health care insurers process over 5 billion claims for payment. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential. The HCPCS Level II Code Set is one of the standard code sets used for this purpose. The HCPCS is divided into two principal subsystems, referred to as level I and level II of the HCPCS. Level I of the HCPCS is comprised of CPT (Current Procedural Terminology), a numeric coding system maintained by the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. These health care professionals use the CPT to identify services and procedures for which they bill public or private health insurance programs. Decisions regarding the addition, deletion, or revision of CPT codes are made by the AMA. The CPT codes are republished and updated annually by the AMA. Level I of the HCPCS, the CPT codes, does not include codes needed to separately report medical items or services that are regularly billed by suppliers other than physicians.

Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the level II HCPCS codes were established for submitting claims for these items. The development and use of level II of the HCPCS began in the 1980's. Level II codes are also referred to as alpha-numeric codes because they consist of a single alphabetical letter followed by 4 numeric digits, while CPT codes are identified using 5 numeric digits.

In October of 2003, the Secretary of HHS delegated authority under the HIPAA legislation to CMS to maintain and distribute HCPCS Level II Codes. As stated in 42 CFR Sec. 414.40 (a) CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes. Within CMS there is a CMS HCPCS Workgroup which is an internal workgroup comprised of representatives of the major components of CMS, as well as other consultants from pertinent Federal agencies. Prior to December 31, 2003, Level III HCPCS were developed and used by Medicaid State agencies, Medicare contractors, and private insurers in their specific programs or local areas of jurisdiction. For purposes of Medicare, level III codes were also referred to as local codes. Local codes were established when an insurer preferred that suppliers use a local code to identify a service, for which there is no level I or level

II code, rather than use a "miscellaneous or not otherwise classified code." The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required CMS to adopt standards for coding systems that are used for reporting health care transactions. We published, in the Federal Register on August 17, 2000 (65 FR 50312), regulations to implement this part of the HIPAA legislation. These regulations provided for the elimination of level III local codes by October 2002, at which time, the level I and level II code sets could be used. The elimination of local codes was postponed, as a result of section 532(a) of BIPA, which continued the use of local codes through December 31, 2003.

B. HCPCS LEVEL II CODES

The regulation that CMS published on August 17, 2000 (45 CFR 162.10002) to implement the HIPAA requirement for standardized coding systems established the HCPCS level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions that are not identified by the HCPCS level I, CPT codes. The HCPCS level II coding system was selected as the standardized coding system because of its wide acceptance among both public and private insurers. Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002. The purpose of this section is to provide a general description of the current HCPCS level II coding system.

The HCPCS level II coding system is a comprehensive and standardized system that classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. For each alphanumeric HCPCS code, there is descriptive terminology that identifies a category of like items. These codes are used primarily for billing purposes. For example, suppliers use HCPCS level II codes to identify items on claim forms that are being billed to a private or public health insurer.

HCPCS is a system for identifying items and services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment.

Currently, there are national HCPCS codes representing over 4,000 separate categories of like items or services that encompass millions of products from different manufacturers. When submitting claims, suppliers are required to use one of these codes to identify the items they are billing. The descriptor that is assigned to a code represents the definition of the items and services that can be billed using that code. To avoid any appearance of endorsement of a particular product through HCPCS, the descriptors that are used to identify codes do not refer to specific products. For this reason, brand or trade names are not used to describe the products represented by a code.

In summary, the HCPCS level II coding system has the following characteristics:

- This system ensures uniform reporting on claims forms of items or services that are medical in nature. Such a standardized coding system is needed by public and private insurance programs to ensure the uniform reporting of services on claims forms by suppliers and for meaningful data collection.

- The descriptors of the codes identify a category of like items or services rather than specific products or brand/trade names.
- The coding system is not a methodology for making coverage or payment determinations. Each payer makes determinations on coverage and payment outside this coding process.

C. TYPES OF HCPCS LEVEL II CODES

There are several types of HCPCS level II codes depending on the purpose for the codes and who is responsible for establishing and maintaining them.

Permanent National Codes

National permanent HCPCS level II codes are maintained by the CMS HCPCS Workgroup. The Workgroup is responsible for making decisions about additions, revisions, and deletions to the permanent national alpha-numeric codes. These codes are for the use of all private and public health insurers. Since HCPCS is a national coding system all payers will be represented in the Workgroup including representatives from private insurance agencies, the Statistical Analysis Durable Medical Equipment Regional Carriers (SADMERC), and Medicaid will participate in the workgroup meetings and provide input as to what is necessary to meet each party's program operating needs.

The permanent national codes serve the important function of providing a standardized coding system that is managed jointly by private and public insurers. This standardized approach to developing a set of uniform codes provides a stable environment for claims submission and processing.

Dental Codes

The dental codes are a separate category of national codes. The Current Dental Terminology (CDT) is a publication copyrighted by the American Dental Association (ADA) that lists codes for billing for dental procedures and supplies. The CDT is included in HCPCS level II. Decisions regarding the revision, deletion, or addition of CDT codes are made by the ADA and not the CMS HCPCS Workgroup.

As the Department of Health and Human Services has an agreement with the AMA pertaining to the use of the Current Procedural Terminology (CPT) codes for physician services, it also has an agreement with the ADA to include CDT as a set of HCPCS level II codes for use in billing for dental services.

Miscellaneous Codes

National codes also include "miscellaneous/not otherwise classified" codes. These codes are used when a supplier is submitting a bill for an item or service and there is no existing national code that adequately describes the item or service being billed. The importance of miscellaneous codes is that they allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA) even though there is no distinct code that describes the service or item. A miscellaneous code can be used during the period of time a request for a new code is being considered under the HCPCS review process. The use of miscellaneous codes also helps us to avoid the inefficiency and administrative burden

of assigning distinct codes for items or services that are rarely furnished or for which we expect to receive few claims.

Because of miscellaneous codes, the absence of a specific code for a distinct category of products does not affect a supplier's ability to submit claims to private or public insurers and does not affect patient access to products. Claims with miscellaneous codes are manually reviewed, the item or service being billed must be clearly described, and pricing information must be provided along with documentation to explain why the item or service is needed by the beneficiary.

Ordinarily, before using a miscellaneous code on a claim form, a supplier should check with the entity that will receive the payment claim to determine whether there is a specific code that should be used rather than a miscellaneous code. In the case of claims that are to be submitted to one of the four durable medical equipment regional carriers (DMERCs), suppliers that have coding questions should check with the statistical analysis durable medical equipment carrier (SADMERC) under contract to CMS. The SADMERC is responsible for providing suppliers and manufacturers with assistance in determining which HCPCS code should be used to describe DMEPOS items for the purpose of billing Medicare. The SADMERC has a toll free helpline for this purpose, (877) 735-1326, which is operational during the hours of 9 AM to 4 PM (EST) In addition, The SADMERC publishes a product classification list on its website that lists individual items to code categories. More information about the SADMERC and the SADMERC's product classification list can be found at http://www.palmettogba.com.

If no code exists that describes the product category to which the item belongs, and if the item fits a Medicare Benefit Category, the SADMERC may instruct the supplier to submit claims using a "miscellaneous/not otherwise classified" code. If an item does not fit a Medicare Benefit Category, the SADMERC might assign a code that indicates that the product is not covered by Medicare for example, code A9270, NON-COVERED ITEM OR SERVICE. If an item is included or bundled into another code and not separately reimbursed by Medicare, the SADMERC may assign the code that includes the item or a code that indicates that the item is included as a component of another code. In those cases in which a supplier or manufacturer has been advised to use a miscellaneous code because there is no existing code that describes a given product, and the supplier or manufacturer believes that the code is needed, it should submit a request to modify the HCPCS in accordance with the established process. The process for requesting a revision to the HCPCS level II codes is explained below.

Temporary National Codes

Temporary codes are for the purpose of meeting, within a short time frame, the national program operational needs of a particular insurer that are not addressed by an already existing national code. The CMS HCPCS Workgroup has set aside certain sections of the HCPCS code set to allow the Workgroup to develop temporary codes. Decisions regarding the number and type of temporary codes and how they are used are also made by the CMS HCPCS Workgroup. These codes are used at the discretion of CMS. This means that if, before the next scheduled annual update for permanent codes, the CMS HCPCS Workgroup needs a code in order to meet specific operating needs that pertain to its particular programs, it may establish a national temporary code. In the case of Medicare, decisions regarding temporary codes are made by the CMS

HCPCS workgroup. For example, Medicare may need additional codes before the next scheduled annual HCPCS update to implement newly issued coverage policies or legislative requirements. Although we establish temporary codes to meet our specific operational needs, the temporary codes we establish can be used by other insurers. Temporary codes allow insurers the flexibility to establish codes that are needed before the next January 1 annual update for permanent national codes or until consensus can be achieved on a permanent national code. Permanent national codes are only updated once a year on January 1.

The CMS HCPCS Workgroup may decide to replace temporary codes with permanent codes. However, temporary codes do not have established expiration dates. Whenever a permanent code is established by the CMS HCPCS Workgroup to replace a temporary code, the temporary code is deleted and cross-referenced to the new permanent code.

Types of temporary HCPCS codes:

- The C codes were established to permit implementation of section 201 of the Balanced Budget Refinement Act of 1999. The C codes identify items that may qualify for "pass through" payments under the hospital outpatient prospective payment system (HOPPS). These codes are used exclusively for the HOPPS purposes and are only valid for Medicare on claims submitted by hospital outpatient departments. More information regarding HOPPS can be found at http://www.cms.hhs.gov/providers/hopps/.
- The G codes are used to identify professional health care procedures and services that would otherwise be coded in CPT-4 but for which there are no CPT-4 codes.
- The Q codes are used to identify services that would not be given a CPT-4 code, such as drugs, biologicals, and other types of medical equipment or services, and which are not identified by national level II codes but for which codes are needed for claims processing purposes.
- The K codes were established for use by the DMERCs when the currently existing permanent national codes do not include the codes needed to implement a DMERC medical review policy. For example, codes other than the permanent national codes may be needed by the DMERCs to identify certain product categories and supplies necessary for establishing appropriate regional medical review coverage policies.
- The S codes are used by private insurers to report drugs, services, and supplies for which there are no national codes but for which codes are needed by the private sector to implement policies, programs, or claims processing. They are for the purpose of meeting the particular needs of the private sector. These codes are also used by the Medicaid program, but they are not payable by Medicare.
- Certain H codes are used by those State Medicaid agencies that are mandated by State law to establish separate codes for identifying mental health services such as alcohol and drug treatment services.
- The T codes are designated for use by Medicaid State agencies to establish codes for items for which there are no permanent national codes and for which codes are necessary to meet a national Medicaid program operating need. T codes are not used by Medicare but can be used by private insurers.

Code Modifiers

In some instances, insurers instruct suppliers that a HCPCS code must be accompanied by code modifier to provide additional information regarding the service or item identified by the HCPCS code. Modifiers are used when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service. For example, a UE modifier is used when the item identified by a HCPCS code is "used equipment," a NU modifier is used for "new equipment." The level II HCPCS modifiers are either alpha-numeric or two letters.

C. REQUESTING A REVISION TO THE HCPCS LEVEL II CODES

Anyone can submit a request for modifying the HCPCS level II national code set. A document explaining the HCPCS revision process, as well as a detailed format for submitting a request, is available on the HCPCS website at http://www.cms.hhs.gov/medicare/hcpcs. Besides the information requested in this format, a requestor should also submit any additional descriptive material, including the manufacturer's product literature and information, that it thinks would be helpful in furthering our understanding of the medical features of the item for which a coding revision is being recommended. The HCPCS coding review process is an ongoing continuous process. Requests may be submitted at any time throughout the year. Requests that are received and complete by January 3 of the current year will be considered for inclusion in the next annual update (January 1st of the following year). Requests received on or after January 3, and requests received earlier that require additional evaluation, will be included in a later HCPCS update. There are three types of coding revisions to the HCPCS that can be requested:

1. That a permanent code be added
   When there is not a distinct code that describes a product, a code may be requested (1) if the FDA allows the product to be marketed in the United States and (2) if the product is not a drug, the product has been on the market for at least 3 months; if the product is a drug, there is no requirement to submit marketing data; and (3) the product represents 3 percent or more of the outpatient use for that type of product in the national market. If a request for a new code is approved, the addition of a new HCPCS codes does not mean that the item is necessarily covered by any insurer. Whether an item identified by a new code is covered is determined by the Medicare law, regulations, and medical review policies and not by the assignment of a code.

2. That the language used to describe an existing code be changed
   When there is an existing code, a recommendation to modify the code can be made when an interested party believes that the descriptor for the code needs to be modified to provide a better description of the category of products represented by the code.

3. That an existing code be deleted

When an existing code becomes obsolete or is duplicative of another code, a request can be made to delete the code.

When there is no currently existing code to describe a product, a miscellaneous code/not otherwise classified code may be appropriate. The use of a miscellaneous code permits a claims

history to be established for an item that can be used to support the need for a national permanent code.

Requests for coding revisions should be sent to the following:
Alpha-Numeric HCPCS Coordinator,
Center for Medicare Management,
Centers for Medicare and Medicaid Services,
C5-08-27,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

CMS HCPCS Workgroup
The CMS HCPCS Workgroup is an internal workgroup comprised of representatives of the major components of CMS, the Medicaid State agencies, and the SADMERC. The SADMERC represents Medicare program operating needs with input from the four DMERCs which have responsibility for processing Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) claims for the Medicare program. Coding decisions are coordinated with both public and private insurers. The CMS HCPCS workgroup considers each coding request, and beginning with the 2006 cycle, will determine whether HCPCS coding requests warrant a change to the national permanent codes. Prior to the 2006 cycle, the National Panel was responsible for final decisions.

When a recommendation for a revision to the HCPCS is received, it is reviewed at a regularly scheduled meeting of the CMS HCPCS Workgroup. Ordinarily, the CMS HCPCS Workgroup meets monthly to discuss whether coding requests warrant a change to the national permanent codes.

Evaluating HCPCS Coding Requests
The CMS HCPCS workgroup applies the following criteria to determine whether there is a demonstrated need for a new or modified code or the need to remove a code:

1. When an existing code adequately describes the item in a coding request, then no new or modified code is established. An existing code adequately describes an item in a coding request when the existing code describes products with the following:
    - Functions similar to the item in the coding request.
    - No significant therapeutic distinctions from the item in the coding request.
2. When an existing code describes products that are almost the same in function with only minor distinctions from the item in the coding request, the item in the coding request may be grouped with that code and the code descriptor modified to reflect the distinctions.
3. A code is not established for an item that is used only in the inpatient setting or for an item that is not diagnostic or therapeutic in nature.
4. A new or modified code is not established for an item unless the FDA allows the item to be marketed. FDA approval documentation is required to be submitted with the coding request application for all non-drug items. For drugs, FDA approval documentation will be accepted up to March 31 following the application deadline as long as the application is otherwise complete and submitted by the deadline.

5. There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code.
6. The determination to remove a code is based on the consideration of whether a code is obsolete (for example, products no longer are used, other more specific codes have been added) or duplicative and no longer useful (for example, new codes are established that better describe items identified by existing codes). In developing its decisions, the HCPCS Workgroup uses the criteria mentioned above. In deciding upon a recommendation, the workgroup does not include cost as a factor.

Opportunity for Public Input/Public Meeting Process for HCPCS
On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106-554. Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new DME under Medicare Part B of title XVIII of the Social Security Act (the Act). As part of HCPCS reform, CMS expanded the public meeting forum to include all public requests as of the 2005-2006 coding cycle. Accordingly, CMS hosts annual public meetings that provide a forum for interested parties to make oral presentations and/or to submit written comments in response to preliminary coding and pricing recommendations for new durable medical equipment that have been submitted using the Healthcare Common Procedure Coding System coding revision process. Agenda items for the meetings will be published in advance of the public meeting on the HCPCS website at http://www.cms.hhs.gov/medicare/hcpcs. The agenda will include descriptions of the coding requests, the requestor, and the name of the product or service. This change will provide more opportunities for the public to become aware of coding changes under consideration, as well as opportunities for public input into decision-making.

The HCPCS coordinator schedules meetings with interested parties, at their request, as time permits, to discuss their recommendations regarding possible changes to the HCPCS level II codes. These meetings are held at the Central Office of CMS. In addition to representatives from the CMS HCPCS Workgroup, staff from Medicaid and Medicare coverage, payment and operations are invited to attend these meetings. These meetings are not related to the meetings mandated by section 531(b) of BIPA, they are also not decision making meetings or CMS HCPCS Workgroup meetings.

Final Decisions
The CMS HCPCS Workgroup is responsible for making the final decisions pertaining to additions, deletions, and revisions to the HCPCS codes. The CMS HCPCS Workgroup reviews all requests for coding changes and makes final decisions regarding the annual update to the national codes. The Workgroup sends letters to those who requested coding revisions to inform them of the Workgroup's decision regarding their coding requests. The decision letters include, but may not be limited to, the following types of responses:

1. A change to the national codes has been approved that reflects, completely or in part, your coding request.
2. Your request for a coding revision to this year's update has not been approved because the scope of your request necessitates that additional consideration be given to your request before the CMS HCPCS Workgroup reaches a final decision.
3. Your reported sales volume was insufficient to support your request for a revision to the national codes. To determine whether there is sufficient sales volume to warrant a permanent code, we ask requestors to submit 3 months of the most recent sales volume for non-drug items. There is not a requirement to submit marketing data for drugs.
4. Your request for a new national code has not been approved because there already is an existing permanent or temporary code that describes your product.
5. Your request for a code has not been approved because your product is not used by health care providers for diagnostic or therapeutic purposes.
6. Your request for a code has not been approved because the code you requested is for capital equipment.
7. Your request for a code has not been approved because your product is an integral part of another service and payment for that service includes payment for your product; therefore, your product may not be billed separately to Medicare.
8. Your request for a revision to the language that describes the current code has not been approved because it does not improve the code descriptor.
9. Your request for a new code has not been approved because your product is not primarily medical in nature (for example, generally not useful in the absence of an illness or injury).
10. Your request for a code has not been approved because your product is used exclusively in the inpatient hospital setting.
11. Your request for a code has not been approved because it is inappropriate for inclusion in the HCPCS Level II code set and request should be submitted independently to another coding authority (e.g. AMA for CPT coding, ADA for CDT coding, etc.)

Decision letters also inform the requestors that they may contact the entity in whose jurisdiction a claim is filed for assistance in answering any coding questions. For Medicare, contact the SADMERC. Under contract to CMS, the SADMERC is responsible for providing suppliers and manufacturers with assistance in determining which HCPCS code should be used to describe DMEPOS items for the purpose of billing Medicare. The SADMERC has a toll free helpline for this purpose, (877) 735-1326, which is operational during the hours of 9 AM to 4 PM (EST) For Medicaid, contact the state Medicaid agency. For private insurance, contact the individual insurer. A requestor who is dissatisfied with the final decision may submit a new request asking the CMS HCPCS Workgroup to reconsider and re-evaluate the code request. At that time, the requestor should include new information or additional explanations to support the request.

Reconsideration Process

CMS management is considering pilot-testing, a process by which denied applicants would be allowed an opportunity to have their application reconsidered during the same coding cycle. The

basis for denial will be clearly delineated in a notice to the applicant and provided in a timely fashion. This pilot is expected to be introduced during the 2007 coding cycle.

D. HCPCS Updates

Permanent National Codes
The national codes are updated annually, according to the following schedule:
1. Coding requests have to be received by January 3 of the current year to be considered for the next January 1 update of the subsequent year. This means that completed requests must be received by no later than January 3 of the current year to be considered for inclusion in the January update of the following year unless January 3 falls on a weekend; then the due date is extended to the following Monday.
2. Computer tapes and instructions, that include an updated list of codes and identify which codes have been changed or deleted, are updated and sent to our contractors and Medicaid State agencies at least 60 days in advance of the January 1 implementation date for the annual update. In addition, the CMS HCPCS Workgroup's final decisions on all public requests for changes to the HCPCS coding system will be published on the official HCPCS web site at www.cms.hhs.gov/medicare/hcpcs in November of each year.

Temporary Codes
Temporary codes can be added, changed, or deleted on a quarterly basis. Once established, temporary codes are usually implemented within 90 days, the time needed to prepare and issue implementation instructions and to enter the new code into CMS's and the contractors' computer systems and initiate user education. This time is needed to allow for instructions such as bulletins and newsletters to be sent out to suppliers to provide them with information and assistance regarding the implementation of temporary CMS codes.

HCPCS/Medicare Website
Our website, http://www.cms.hhs.gov/medicare/hcpcs lists all of the current HCPCS codes, an alphabetical index of HCPCS codes by type of service or product, and an alphabetical table of drugs for which there are level II codes. The website also includes a list of applications submitted in the current coding cycle. Interested parties can submit comments regarding the agenda items to the CMS HCPCS Workgroup by sending an e-mail to CMS through this website. These comments are included as part of the Workgroup's review as it considers the coding requests.

The newly established temporary codes and effective dates for their use are also posted on the HCPCS website at http://www.cms.hhs.gov/medicare/hcpcs. This website enables us to quickly disseminate information on coding requests and decisions.

Code Assignment Following Medicare National Coverage Determination
Pursuant to Sec. 1862 (l) (3) (C) (iv) of the Social Security Act (added by Section 731 (a) of the Medicare Modernization Act), the Centers for Medicare and Medicaid Services (CMS), has developed a process by which the CMS HCPCS Workgroup will identify an appropriate existing code category and/or establish a new code category to describe the item that is the subject of a

National Coverage Determination (NCD). If the item is considered Durable Medical Equipment, Prosthetic, Orthotic or Supply (DMEPOS), the CMS will defer to the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) to determine the appropriate code category. Under contract to the CMS, the SADMERC assigns individual DMEPOS products to HCPCS code categories for the purpose of billing Medicare.

As a matter of meeting on-going Medicare program operating needs, processes have existed for some time by which items and services that are newly covered by Medicare are assigned to a new or existing code category. Effective July 1, 2004, the process outlined below has been used by CMS to comply with the requirements of Sec. 1862 (l).

1. Assignment of an Existing "Temporary" or "Permanent" Code: When the CMS determines that an item is already identified by an existing "temporary" or "permanent" (as described in A and B above) HCPCS code category, but was previously not covered, the CMS will assign the item to the existing code category, and ensure that the coverage indicator assigned to the code category accurately reflects Medicare policy regarding payment for the item. Sec. 731 of the MMA does not require that a new code category or a product specific code be created for an item simply because a new coverage determination was made, without regard to codes available in the existing code set.
2. Assignment of a New "Temporary" or "Permanent" Code: When the CMS determines that a new code category is appropriate, CMS will make every effort to establish, publish, and implement the new code at the time the final coverage determination is made.
3. Assignment of an Unclassified Code: Under certain circumstances, the assignment of an item to an unclassified code may be necessary. A number of unclassified codes already exist under various headings throughout the HCPCS Level II code set. When an item is newly covered, but usage is narrow and the item would be billed infrequently, it may be more of an administrative burden to revise the code set than to use an unclassified code along with other, existing processing methods. When a new "temporary" or "permanent" code is appropriate, but the change cannot be implemented and incorporated into billing and claims processing systems at the time the final NCD decision memorandum is released, an unclassified code may be assigned in the interim, until a new code can be implemented, in order to ensure that claims can be processed for the item. The timing of implementation of new "temporary" or "permanent" codes relative to the date of the coverage determination depends on a variety of factors, some of which are not within the direct control of the code set maintainers, for example:
    - coding alternatives may require extensive research;
    - the timing of the coverage determination may be such that the publication deadline for the next Quarterly Update is missed
    - there is insufficient time between NCD and Quarterly Update to incorporate new codes into new policy and accompanying billing instructions, and into claims processing systems along with any edits needed to operationalize the new code.

Rev. November 30, 2005

EXHIBIT 2

American Medical Technologies

March 15, 2007

From: Heather Hettrick PT, PhD, CWS, MLT, FCCWS
Director of Clinical Education
AMT, Inc.

To whom it may concern:

I have been asked to provide professional comment on the nature of composite surgical dressings, both with and without an adhesive border. Please see my comments below after the specific questions that were posted.

(A) The Medical Directors for the PSC's believe that if the adhesive border is removed from a composite dressing it compromises the bacteria shield of the dressing and since that is a requirement, the non-bordered composite does not meet the criteria listed for "composite dressings."

By definition, a composite dressing is manufactured by combining two or more distinct products with several functions. Composite dressings feature a bacterial barrier; an absorptive layer (other than alginate, foam, hydrocolloid, or hydrogel); a semiadherent or nonadherent property for covering the wound; and some composites have an adhesive border.

Whether the composite has an adhesive border or not, does not change the effectiveness of the dressing. Rather, an adhesive border may make the dressing more "user- friendly" and convenient in that it requires less work and time by the caregiver or clinician to secure the dressing as it has a built in adhesive (or border) to secure to the periwound. The adhesive border has no bearing on the bacterial shield provided by the dressing. The bacterial shield is provided by the impermeable film coating on the composite dressing whether it has an adhesive border or not.

(B) Clinically, can the required bacteria shield's integrity be maintained by using various adhesive tape and picture-framing the dressing? Why?

Yes! Window framing the composite with tape, securing it with roll gauze or gauze netting all provide a method of securing the dressing into place to cover the wound to allow the dressing to protect and absorb. The only difference between bordered composites and non bordered composites is the convenience factor for the clinician or caregiver.

20361 Irvine Ave. Santa Ana Heights, California 92707
Phone: 800-232-9266
Fax: 800-232-9268

Composites can be used as primary or secondary dressings on partial or full thickness wounds with minimal to heavy exudate, healthy granulation tissue, wounds with slough or moist eschar or wounds with mixed wound beds. Composites by nature, facilitate autolytic debridement, allow for moisture vapor exchange, conform well to body contours, can be safely used on infected wounds and are easy to apply and remove. As long as the dressing is being used and applied appropriately, the bacterial shield provided by the composite is unchanged regardless of its method of attachment.

(C) Clinically, if gauze is used to hold the "non-bordered" composite dressing in place, is the bacteria shield's integrity compromised?

The composites' bacterial shield is essentially built into the dressing itself. This is by definition a composite, the combination of two distinct dressings. Composites protect the wound bed from contamination by the film coating that is part of the dressing. This coating is the "shield" and as long as the dressing is applied appropriately and secured (whether with tape or gauze) the wound should be protected from exogenous bacterial invasion to the same degree as a dressing with an adhesive border.

Should you have further questions, please feel free to contact me at 646.408.4011.

Thank you for your time and consideration,

Regards,

Heather Hettrick

20361 Irvine Ave. Santa Ana Heights, California 92707
Phone: 800-232-9266
Fax: 800-232-9268

AMERICAN MEDICAL TECHNOLOGIES, INC.

To Whom It May Concern,

I wanted to take a moment and comment on the functionality of a non bordered composite dressing and the so called "bacterial barrier".

STATEMENT The Medical Directors for the PSC's believe that if the adhesive border is removed from a composite dressing it compromises the bacteria shield of the dressing and since that is a requirement, the non-bordered composite does not meet the criteria listed for "composite dressings.

RESPONSE Wound dressings of this category assist in creating a favorable microenvironment by protecting the wound from exogenous bacteria loads, allowing for a controlled gaseous/vapor exchange, providing and maintaining a moist wound environment, preventing drainage strike-through by absorbing exudate, relieving pain, and assisting in the production of granulation tissue.

While an adhesive border on many dressings may contribute to the bacterial shield it is only part of a larger matrix in preventing bioburden overload, colonization and ultimately infection. Clinically, all wounds are contaminated. This is due to self contamination by the natural skin flora of the patient's body. Even after cleansing, bacteria may be found on the surface of the wound. Certainly the adhesive application will reduce penetration and possible proliferation of exogenous bacteria. However it is not the only factor in barrier protection.

Non bordered composite dressings may contain an absorbent center pad that is placed on a moisture barrier film backing. These types of material backings contribute to the bacterial barrier and are of equal or greater importance in describing the bacterial barrier than the absorptive properties of the dressing in controlling exudate and reducing the climate for bacterial proliferation, drawing bacteria away from the wound and preventing maceration of the surrounding tissue. This is especially true in chronic wounds where exudate may serve as a growth media for bacteria. The wicking or absorption ability of the dressing contributes to a positive microenviroment and acts as part of the bacterial barrier.

Specialists in Wound Care Risk Management
20361 IRVINE AVE.
SANTA ANA HEIGHTS,
CALIFORNIA 92707
PHONE 800-232-9266
FAX 800-232-9268

QUESTION Clinically, can the required bacteria shield's integrity be maintained by using various adhesive tape and picture-framing the dressing?

RESPONSE In the wound management context, the terms 'adherent' and 'adhesive' are sometimes used interchangeably. This causes confusion and can lead to a misunderstanding of the properties of the products concerned. The term 'adherence' describes the interaction between a dressing and the wound, while the term 'adhesive' should be used to describe the interaction that takes place between the dressing and the intact peri-wound skin.

Non-adherent wound contact dressings such as non bordered composite dressing are often used in conjunction with tapes and secured by window framing around the edge of the dressing (adhesion) When used in this manner, the tape acts as part of the above described bacterial barrier. The advantage of securing a dressing utilizing this method is that the window framed area is extended out and away from the wound and/or immediate periwound area as the tape is applied to mature tissue.

A clinician's choice of a dressing should also be based on the appropriate size of dressing. When applied, the dressing edge must be a sufficient distance from the wound edge and/or the periwound tissue. This will reduce traumatic damage to the newly forming tissues and epithelium during the healing process and help reduce the possibility of strike-through. Inappropriate size dressings can impact application and removal of the dressing thereby extending healing times especially in the elderly patient whose skin is particularly fragile.

QUESTION Clinically, if gauze is used to hold the "non-bordered" composite dressing in place, is the bacteria shield's integrity compromised?

RESPONSE Use of the window framing technique to secure a gauze dressing does contribute to the maintenance of the bacterial barrier. Again it is only one component of the barrier by securing the edges of the dressing reducing penetration of exogenous bacteria. Another method of securing a dressing is the use of roll gauze. Roll gauze is used in acute wound care or primary injury (first responders) to chronic wound care. It is frequently used as a secondary dressing to maintain a primary dressing such as a non bordered composite in place. When used as a secondary dressing it certainly conceivable that it will assist in maintaining the bacterial barrier as well as protecting the patient's skin from trauma, tissue damage and in pain management since both primary and secondary dressing have no adhesive properties in contact with skin tissue. Use of the roll gauze assists in preventing strike-through should a primary dressing be overwhelmed by exudate and prevents edge curl of the primary dressing due to its compressive ability. This certainly lends itself to being a component of the bacterial barrier.

Respectfully:

Charles F. Gokoo MD

Charles F. Gokoo MD CMO, CWS, FACCWS

LSU Health Sciences Center
SCHOOL OF ALLIED HEALTH PROFESSIONS
Office of the Dean

School of Medicine in Shreveport
School of Allied Health Professions
School of Graduate Studies

March 19, 2007

To Whom It May Concern:

This letter is being sent in response to several queries by the Medical Directors for the PSC. Specifically, the questions and responses are as follows:

QUESTION: The Medical Directors for the PSC's believe that if the adhesive border is removed from a composite dressing it compromises the bacteria shield of the dressing and since that is a requirement, the non-bordered composite does not meet the criteria listed for "composite dressings."

The adhesive shields of most bordered dressings, including composites, is provided primarily as a means of convenience to minimize the need for other forms of securement at dressing application. The periwound skin is a contaminated environment inoculated with a variety of normal flora. By placing any securing or adhesive layer in contact with such skin results in the layer also being exposed to the bacteria. In most instances, dressings are applied with a "clean" technique which implies that the clinician or caregiver is using clean examining gloves, not sterile ones. In such instances, the gloved hands frequently come in contact with the adhesive border of the dressing, but not with the center sterile portion that contacts the wound base. The clinician is most concerned with the state of the wound underlying the composite dressing. Once the wound is cleansed and dressed, any form of securement then serves the purpose of maintaining the moist wound environment and preventing the introduction of exogenous bacteria to the wound bed. Adhesive tape, and a variety of other forms of securement, provide a physical barrier for the introduction of such bacteria. In addition, the ability of the clinician to use tape to window-frame a composite dressing provides for a significant reduction in cost without any compromise to the dressing provided to the patient.

QUESTION: Clinically, can the required bacteria shield's integrity be maintained by using various adhesive tape and picture-framing the dressing?

Most bordered composite dressings consist of a non-adherent wound layer with an adherent wound border. The non-adherent wound layer is designed to absorb

Louisiana State University Health Sciences Center • School of Allied Health Professions • Office of the Dean
1501 Kings Highway • P.O. Box 33932 • Shreveport, Louisiana 71130-3932
phone (318) 675-6800 fax (318) 675-4783 www.lsuhsc.edu

wound exudate and prevent it from striking out to the borders of the dressing. If exudation is severe, to the point that the central dressing cannot contain it, the fluid comes in contact with the peripheral adhesive border. At this point, the dressing typically fails as it is not capable of handing moisture from the under surface. Moisture coming in contact with the outer surface of an adhesive dressing however does not tend to cause the same failure in the seal. This holds true for other forms of adherence such as adhesive tapes. As long as the moisture remains on the outside of the tapes, they provide the necessary adherence to keep the dressing in place. Furthermore, many forms of adhesive tape have an additional property of being water repellant.

QUESTION: Clinically, if gauze is used to hold the "non-bordered" composite dressing in place, is the bacteria shield's integrity compromised?

If gauze is placed over any type of dressing, including a non-bordered composite, it provides another layer of physical barrier for the passage of bacteria. This remains the case as long as the outer layer remains dry. Should the outer layer of gauze become wet and there not be a water proof layer beneath it, this would then provide a pathway for the migration of bacteria. This, however, is no different than would occur with any type of dressing where saturation of the dressing is continuous from wound bed to the outside environment. As long as the non-bordered composite is constructed in such a manner as to have an absorbent, occlusive component, covering with a gauze outer covering should have no adverse affect.

Should you have additional questions regarding this subject, I would be happy to entertain them.

Sincerely,

Joseph McCulloch, PhD, PT, CWS, FCCWS
Dean

CENTRAL PENNSYLVANIA

PODIATRY ASSOCIATES, P.C.

Donald E. Mrdjenovich, D.P.M. • Gerald E. Gronborg, D.P.M. • Seth A. Kearney, D.P.M.

2727 Beale Avenue • Altoona, PA 16601 • 814.946.1075 fax: 814.946.4076
10455 Lincoln Highway • Everett, PA 15537 814.623.3513 • fax 814.623.3593
1012 Bigler Avenue, PO Box 292 • Northern Cambria, PA 15714 • 814.948.4000 fax: 814.948.2021
2040 Quakertown Road, PO Box 123 • Fishertown, PA 15539 • 814.623.3513 • fax 814.623.3593
www.foothaven.com

To whom it may concern:

Subject: Professional comment on composite dressings, both with and without an adhesive border.

QUESTION The Medical Directors for the PSC's believe that if the adhesive border is removed from a composite dressing it compromises the bacteria shield of the dressing and since that is a requirement, the non-bordered composite does not meet the criteria listed for "composite dressings

Bordered and non-bordered composite secondary dressings can be used over a wide range of primary dressings and for a wide variety of wounds. These range from friable, immaturely healed wounds to heavily exuding wounds. These types of dressings have a versatile purpose. They serve to protect, decrease friction, control exudate and maintain a moist physiological environment.

It is a well-accepted fact that maintaining a moist wound environment not only accelerates wound healing, but also promotes infection control. The bacterial control, however, lies within the function of the composite foam or absorbent center pad dressing with a moisture barrier film backing. These serve as a bacterial barrier by controlling wound exudates. Thus, reducing the environment of bacterial proliferation and protecting the periwound tissue.

Research has long established that controlling and maintaining a moist wound environment is shown to be the most important physiological factor to healing. However, changes to the local wound environment itself are of equal importance. This is accelerated often with the combined use of primary dressings such as hydro gels, growth factors, enzymatic agents, antimicrobials and hydro fibers which work to not only hydrate the wound, but can insulate and reduce pain to the wound, promote autolytic debridement and also serve to decrease infection.

The application of an adhesive border of a composite dressing may contribute to the shielding of exogenous bacteria from the wound, however, as described above the role of adhesive is secondary to the actual function of the types of material backing or primary agents used in wound dressing. This is especially true in the chronic wound where exudate may serve as a growth media for bacteria.

QUESTION Clinically, can the required bacteria shield's integrity be maintained by using various adhesive tape and picture framing the dressing?

The required bacteria shield's integrity can certainly be maintained by using various adhesive tape products and 'picture-framing' the dressing. Non-adherent wound dressings are often 'picture-framed' to maintain a seal between the dressing, the wound and the surrounding healthy periwound. In fact, many of the adhesive products used are of similar materials that are integrated into the bordered composite dressings. Doing this provides stability to the dressing in certain awkward anatomical areas. It also prevents unwanted dehydration and/or saturation of the wound with exudates. Maintaining a good contact layer decreases the potential bacterial growth by allowing the non-bordered composite dressing to manage exudates to its full potential. This 'picture-framed' seal also avoids drainage onto healthy tissue or skin. We often experience this with Stage III or IV pressure ulcers, or foot and ankle wounds, where the size, location, character and activity of the ulcer lends itself to a higher degree of drainage, higher risk for infection and a higher incidence of pain and discomfort. The clinician cannot be limited only to the available bordered composite dressing, but must have the ability to customize these dressings to specific anatomical areas and wound sizes. The dressing borders must be a sufficient distance from the wound edge and avoid trauma to the periwound tissue. Thus, obtaining optimal wound protection, environment, healing and reducing waste of product.

Question Clinically, if gauze is used to hold the "non-bordered" composite dressing in place, is the bacteria shield's integrity compromised?

Gauze can, and should, in many circumstances be used to hold the "non-bordered" composite dressing in place. This will maintain the bacteria shield integrity. The factors and parameters of wound healing for many patients are extremely dynamic and sensitive to changes in physiological state of well-being. The wound patient is often in a state of compromised vasculature, nutrition, endocrine and renal status. Additionally, they present with various mobility issues, all, which influence their healing. A clinician must be prudent and have the ability to assess these patients individually. Often the non-bordered composite dressing is held in place by roll gauze when the patient is experiencing conditions causing the skin to become friable and unsafe for use of any type of adhesive. Other patients may have issues of limb edema. In these patients a roll gauze type dressing will be used to maintain the position of the non- bordered composite dressing. This may then be integrated into a multi-layer resistive dressing to reduce

edema and bio-burden. The bacterial seal is maintained as explained earlier by controlling exudates, and maintaining a moist wound environment and contact layer.

In conclusion, numerous conditions affect the local environment in which wounds heal. In order to manage patient wounds with optimum benefit those factors must be controlled and modified by the clinician. The choice of a bordered composite dressing, non-bordered composite dressing with adhesive windowing, or gauze to maintain position of the non-bordered composite dressing, all contribute to the shielding of exogenous bacteria from the wound. However, this is less important to the actual function of the material of the composite dressings, or the strategy for placement used in wound dressings, to decrease the bacterial environment. Therefore, these must all remain within the armamentarium of the wound clinician to potentiate the most excellent outcomes.

Respectfully,

Donald E. Mrdjenovich, DPM, CWS, FCCWS

EXHIBIT 3

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL TECHNOLOGIES, INC., Plaintiff,	)	
v.	)	Case No. 1:08-cv-00319 (JDB)
MICHAEL O. LEAVITT, Secretary, U.S. Department of Health and Human Services, Defendant.	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

Plaintiff American Medical Technologies, Inc. ("Plaintiff" or "the supplier") is a Medicare supplier of "non-bordered composite dressings." Plaintiff challenges steps taken by various Medicare contractors to require an adhesive border for composite dressings and to designate certain billing codes invalid for purposes of Medicare claims submission. Plaintiff alleges subject matter jurisdiction solely under the federal question statute, 28 U.S.C. § 1331. However, the Medicare statute, 42 U.S.C. §§ 405(h) and 1395ii, expressly bars federal question jurisdiction, and requires Plaintiff to exhaust available administrative appeals remedies and obtain a final decision of the Secretary before filing suit in federal district court under 42 U.S.C. §§ 405(g), 1395ff. But Plaintiff nowhere alleges that it has even filed an administrative appeal of the matters raised in the Complaint, much less that it has obtained the administrative hearing and final decision of the Secretary that is required for judicial review under the Medicare statute's exclusive grant of subject matter jurisdiction.

The Supreme Court has recognized a limited exception to § 405(h)'s bar of federal question jurisdiction "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 19 (2000). This narrow exception clearly does not apply here because Plaintiff can raise all aspects of its claims through the Medicare statute's administrative and judicial review mechanism. In taking the actions challenged by Plaintiff, the Medicare contractors directed suppliers to use alternative billing codes for non-bordered composite dressings. If Plaintiff were to submit Medicare reimbursement claims under the alternative billing codes, it would receive an "initial determination" for each benefit claim, which it could then challenge through the mandatory administrative and judicial review process. 42 U.S.C. § 1395ff(a), (b)(1); 42 C.F.R. § 405.904(a)(2). By contrast, if Plaintiff were allowed to evade § 405(h)'s preclusion of federal question jurisdiction, it would be improperly rewarded for failing to abide by the administrative and judicial review scheme required by Congress.

Judicial review of Plaintiff's claims under the Medicare statute would require a final decision of the Secretary following an administrative hearing. 42 U.S.C. § 1395ff. But, as stated above, Plaintiff does not even allege that it requested an administrative hearing, much less that it obtained a final decision of the Secretary following such hearing, on the matters raised in the Complaint. Since the final decision requirement of § 1395ff is jurisdictional and the Secretary has not waived exhaustion of administrative remedies, the Medicare statute cannot provide subject matter jurisdiction until after Plaintiff pursues its claims through the entire, multi-tiered administrative appeals process and secures a final decision of the Secretary after a hearing.

Moreover, Plaintiff's challenge to the actions of the Medicare contractors is centered on

conflicting medical opinions, the kind of dispute for which the administrative process is especially well-suited. Thus, requiring exhaustion of administrative remedies would further the interests of administrative finality and judicial economy, in addition to enforcing the statutory requirement that parties obtain a final decision of the Secretary after an administrative hearing prior to seeking judicial review under the Medicare statute.

STATUTORY AND REGULATORY BACKGROUND

1. The Medicare statute, 42 U.S.C. § 1395 et seq., sets forth a federal health insurance program for the elderly and disabled. Under Medicare's original, fee-for-service program, Part A authorizes payments for covered inpatient hospital services and other institutional provider services, and is funded by payroll taxes. Id. §§ 1395c, 1395d, 1395i. This case arises under Part B, which is a voluntary program subsidized by enrollee premiums and appropriated monies. Id. §§ 1395j, 1395o, 1395r, 1395t. Part B enrollees receive supplementary medical insurance for "medical and other health services," which include physician services and some durable medical equipment ("DME"), prosthetics, orthotics, and supplies (collectively, "DMEPOS"). Id. §§ 1395k(a)(1), 1395m(j)(5), 1395x(s)(1), (2)(A), (6), (8), & (9). See also 42 C.F.R. Part 410 (scope of Part B benefits). Certain surgical dressings are among the medical supplies that potentially qualify for Part B coverage. 42 U.S.C. §§ 1395m(j)(5)(D), 1395x(s)(5); 42 C.F.R. § 410.36(a)(1).

However, while the statute may generally allow coverage of a given type of medical or other health service, a specific service furnished would be covered only if the particular service is not otherwise excluded from coverage. 42 C.F.R. § 410.12(a). The statute includes a coverage exclusion provision of general applicability, which bars payment for all items and services that

"are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). See also id. § 1395y(a)(1)(B)-(22) (specific exclusions of coverage). The Secretary has broad authority to explicate the "not reasonable and necessary" coverage exclusion and other coverage provisions in case-specific adjudications or through generally applicable rules that may be established by notice and comment rulemaking or in less formal guidance. See Heckler v. Ringer, 466 U.S. 602, 617 (1984). A "national coverage determination" ("NCD") may be issued, which is "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). In addition, a Medicare contractor may issue a "local coverage determination" ("LCD"), which is the contractor's determination as to whether or not a particular item or service is covered locally within the contractor's own limited jurisdiction. Id. § 1395ff(f)(2)(B). Absent a governing NCD or LCD, the contractor applies the "not reasonable and necessary" coverage exclusion and other applicable coverage criteria to the particular factual circumstances of an individual claim for Medicare benefits. 68 Fed. Reg. 63692, 63693 (Sept. 26, 2003) (final rule).

The statute establishes various methods for the determination of payments owing for different covered Part B items and services. See generally 42 U.S.C. § 1395l. See also id. §§ 1395w-4 (fee schedule payment for physician services), 1395m(a) & (h) (special payment rules for DME and prosthetics and orthotics, respectively). The Part B payment for covered surgical dressings is 80 percent of the lesser of the actual charge for the item or the payment amount determined by the fee schedule payment methodology for DME with certain adjustments. Id. § 1395m(i). See also id. § 1395m(a)(2) (DME fee schedule payment requirements); 42

C.F.R. §§ 414.200-414.232 (same).

2. The Secretary, through the Centers for Medicare & Medicaid Services ("CMS"), contracts with local private insurance "carriers" to administer the Part B claims process. 42 U.S.C. § 1395u; 42 C.F.R. § 421.200.[1/] However, DMEPOS benefit claims are administered by four "DME Medicare Administrative Contractors" ("DME MACs") (formerly known as "DME Regional Carriers" or "DMERCs"). 42 U.S.C. §§ 1395m(a)(12), 1395kk-1; 42 C.F.R. §§ 421.210(b), 421.404(c)(2).

Moreover, the statute requires the Secretary to enter into contracts with eligible entities to carry out "Medicare integrity program" functions. See 42 U.S.C. § 1395ddd; 42 C.F.R. § 421.300. Thus, CMS contracted with three "DME Program Safeguard Contractors" ("DME PSCs") that were responsible, from March 1, 2006 through February 29, 2008, for creating Medicare coverage guidelines, formulating LCDs, and conducting medical review and utilization review of claims within their respective jurisdictions. See 42 U.S.C. § 1395ddd(b)(1)-(6); 42 C.F.R. § 421.304. Another Medicare contractor, the Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC"), performs limited coding functions for oral anti-cancer drugs; assists CMS in obtaining manufacturer suggested retail prices for use with the DMEPOS fee schedules; and analyzes data on the utilization of the Healthcare Common Procedure Coding System ("HCPCS") codes in order to determine unreasonable or excessive reimbursement amounts.

[1/] During a six-year transition period, between October 1, 2005 and October 1, 2011, the administrative responsibilities of the various Part B carriers and the Part A "fiscal intermediaries" will be taken over by different "Medicare Administrative Contractors" ("MACs"). 42 U.S.C. § 1395kk-1; 42 C.F.R. § 421.400.

3. Medical supplies and other items of DMEPOS must be furnished "incident to a physician's service" or by a "supplier" that possesses both a valid Medicare supplier number and DMEPOS "billing privileges." 42 U.S.C. §§ 1395m(j)(1), 1395x(d); 42 C.F.R. § 424.57. A DMEPOS supplier must submit a timely electronic claim to the pertinent Medicare contractor (now a DME MAC). 42 C.F.R. §§ 424.32(d), 424.44. Each Part B payment claim for items or services furnished by a physician or supplier must be supported by sufficient information and documentation for the Medicare contractor to determine whether the items or services are covered and the amount of any payment deemed owing. 42 U.S.C. § 1395l(e); 42 C.F.R. § 424.5(a)(6). For medical supplies and other items of DMEPOS, the supplier's electronic claim must include the appropriate HCPCS Level II code. 45 C.F.R. §§ 162.1000(a), 162.1002(b)(3). See also 45 C.F.R. §§ 160.103, 162.100.

4. The Medicare statute and regulations afford program beneficiaries dissatisfied with a reimbursement determination, and any assignee of the individual's Part A or Part B benefit claim or the person's appeal rights, several levels of administrative review and, potentially, judicial review. 42 U.S.C. § 1395ff; 42 C.F.R. Part 405, Subpart I. Upon receipt of a claim for payment for items or services furnished, the Medicare contractor issues a notice of "initial determination" addressing whether the items or services are covered and meet all other payment requirements, and, if so, the amount deemed owing for such items or services. 42 U.S.C. § 1395ff(a)(1); 42 C.F.R. § 405.920.[2/] If the claimant (i.e., the beneficiary or any assignee of the beneficiary's claim) is dissatisfied with some aspect of the initial determination, a

[2/] The supplier is paid directly if it accepted assignment of the beneficiary's claim; otherwise, the beneficiary is paid. 42 U.S.C. § 1395u(b)(3)(B)(ii); 42 C.F.R. §§ 424.53(e), 424.55(a).

"redetermination" may be requested by the same contractor. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. Next, if the claimant is dissatisfied with the contractor's redetermination, a "reconsideration" may be requested by a "qualified independent contractor" ("QIC"). 42 U.S.C. § 1395ff(b)(1)(A) & (c); 42 C.F.R. § 405.960. For claims involving at least $100 in controversy, a still dissatisfied claimant may request a hearing, "as provided in [42 U.S.C. §] 405(b)," before an administrative law judge ("ALJ"). 42 U.S.C. § 1395ff(b)(1)(A), (E) & (d)(1); 42 C.F.R. § 405.1002. Furthermore, the ALJ's decision may be reviewed by the Medicare Appeals Council of the Departmental Appeals Board. 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100. The claimant also may seek judicial review, "as provided in [42 U.S.C. §] 405(g)," of the final agency decision of the ALJ or the Medicare Appeals Council, as applicable, on claims involving at least $1,000 in controversy. 42 U.S.C. § 1395ff(b)(1)(A), (E); 42 C.F.R. § 405.1136.[3/] See also 42 U.S.C. § 1395ff(b)(1)(G) (authorizing "reopening" and revisions of initial determinations under Secretary's regulatory guidelines); 42 C.F.R. §§ 405.980-405.986 (reopening rules).

In addition to the forgoing provisions for administrative and judicial review of the denial of an individual benefit claim, different provisions allow for a facial challenge to a national coverage determination ("NCD") or a local coverage determination ("LCD"). An "aggrieved party" can request review of an NCD by the Departmental Appeals Board ("DAB"), and the DAB's final decision is subject to judicial review. 42 U.S.C. § 1395ff(f)(1); 42 C.F.R. Part 426, Subpart E. Also, an aggrieved party can request review of an LCD by an ALJ; the ALJ's

---

[3/] A claimant's capacity to satisfy the amount in controversy requirements for an ALJ hearing and judicial review is enhanced by provisions that allow for the aggregation of benefit claims. 42 U.S.C. § 1395ff(b)(1)(E)(ii); 42 C.F.R. § 405.1006(e). Other provisions authorize "expedited access to judicial review" under certain conditions. 42 U.S.C. § 1395ff(b)(2); 42 C.F.R. § 405.990.

decision is reviewable by the DAB; and the final decision of the ALJ or the DAB, as applicable, is subject to judicial review. 42 U.S.C. § 1395ff(f)(2); 42 C.F.R. Part 426, Subpart D.

STATEMENT OF THE CASE

1. Plaintiff instituted this action with the filing of its Complaint on February 25, 2008. Plaintiff is a Medicare enrolled supplier of wound care supplies, including non-bordered composite dressings. (Plaintiff's Complaint ("Compl.") at ¶ 7; Defendant's Answer ("Answer") at ¶ 7.)

After furnishing non-bordered composite dressings to Medicare beneficiaries, the supplier submitted Part B reimbursement claims under the HCPCS Level II codes for composite dressings without adhesive borders, A6200, A6201, and A6202. (Compl. at ¶¶ 7, 21; Answer at ¶¶ 7, 21.) The DME MACs and the former DMERCS denied some of Plaintiff's claims for lack of medical necessity. (Compl. at ¶ 22; Answer at ¶ 22.) The supplier filed administrative appeals of the denied claims, and various ALJs ruled for Plaintiff in some cases. (Id.)[4] In reversing some of the claim denials, the ALJs did not adopt the views expressed in the testimony of the former Medical Directors for the three DME PSCs. (Compl. at ¶ 23; Answer at ¶ 23.)

2. In September 2006, various DME PSCs, DME MACs, and DMERCs (collectively, "the DME contractors") issued a Bulletin Article (copy attached as Exhibit A hereto) notifying Medicare suppliers of a revision to the definition of "composite dressings," which was effective October 1, 2006. (Compl. at ¶ 26; Answer at ¶ 26; Exhibit A hereto.) Under the revised definition, the requisite "bacterial barrier" for a composite dressing must encompass

[4] Plaintiff alleges that the ALJs adjudicated approximately 38,000 of its denied reimbursement claims and reversed about 98% of the claim denials. (Compl. at ¶ 22.)

the entire dressing pad including an adhesive border. (Compl. at ¶ 28; Answer at ¶ 28; Exhibit A at 2.) Since the revised definition of "composite dressings" required an adhesive border, the DME contractors' Bulletin Article provided that the HCPCS Level II codes for composite dressings without adhesive borders, A6200, A6201, and A6202, were invalid for Medicare claims submission. (Compl. at ¶ 28; Answer at ¶ 28; Exhibit A at 1.) The Bulletin Article further provided that non-bordered "[d]ressings previously coded as A6200, A6201, and A6202 will be coded as specialty absorptive dressings without adhesive border -- A6251, A6252, and A6253, respectively." (Exhibit A at 2.) Later, in March 2007, the DME contractors issued a Policy Article that incorporated the September 2006 Bulletin Article's revised definition of "composite dressings" and the invalidation of HCPCS codes A6200, A6201, and A6202 for purposes of Medicare claims submission. (Compl. at ¶ 26; Answer at ¶ 26.)

After the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article were issued, Plaintiff continued to submit claims for Medicare reimbursement under HCPCS Level II codes A6200, A6201, and A6202. (Compl. at ¶ 44; Answer at ¶ 44.) There is no allegation in Plaintiff's Complaint that it submitted any claims in accordance with the DME contractors' instruction, in the September 2006 Bulletin Article, that claims for non-bordered dressings should be coded as specialty absorptive dressings without adhesive border under HCPCS codes A6251, A6252, and A6253. (See Exhibit A at 2.)

Some of Plaintiff's claims under HCPCS codes A6200, A6201, and A6202, submitted after the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article, were processed and paid by the DME MACs for Jurisdiction A and Jurisdiction D. (Compl. at ¶ 46; Answer at ¶ 46.) The other two DME MACs, for Jurisdiction B and Jurisdiction C,

rejected some of Plaintiff's claims, under HCPCS codes A6200, A6201, and A6202, as invalidly coded claims under the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article. (Id.)

3. There is no allegation in the Complaint that Plaintiff made any effort to file any administrative appeals challenging the DME contractors' September 2006 Bulletin Article or their March 2007 Policy Article. Instead, Plaintiff tried, without success, various informal means of convincing CMS to countermand the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article. (See Compl. at ¶¶ 31, 32, 39-41; Answer at ¶¶ 31, 32, 39-41.)

Plaintiff then filed this suit alleging that CMS and the DME contractors deprived the supplier of both Medicare reimbursement and its administrative appeal rights in contravention of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 704, 706. (Compl. at ¶¶ 1-4, 54-63.) Specifically, Plaintiff alleges that the DME contractors, in requiring an adhesive border for composite dressings and determining that the HCPCS codes for composite dressings without adhesive borders, A6200, A6201, and A6202, were invalid for Medicare claims submission, violated "CMS's Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures." (Compl. at ¶¶ 33-37, 42, 43, 49-53, 55-57. But cf. Answer at ¶¶ 33-37, 42, 43, 49-53, 55-57.) Plaintiff further alleges that, as a result of the DME contractors' actions, it "has been denied reimbursement totaling $741,442" on 1,714 claims for the period from October 1, 2006 through October 31, 2007. (Compl. at ¶ 45. See also Compl. at ¶ 1 (as a result of the DME contractors' actions, "Secretary denied Plaintiff's claims for Medicare reimbursement"). But cf. Answer at ¶¶ 1, 45.) Moreover, Plaintiff alleges that it has been unlawfully deprived of its administrative appeal rights because two of the DME MACs rejected the supplier's claims as

invalidly coded and thus not subject to administrative appeal. (Complaint at ¶¶ 2, 46-48, 54, 58-60, 62. But cf. Answer at ¶¶ 2, 46-48, 54, 58-60, 62.)

For relief, Plaintiff seeks a declaration that the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article are null and void, and an order preventing further implementation of those provisions and reinstatement of the status quo ante. (Compl. at ¶¶ 64, 67, 68.) Plaintiff also requests an order requiring reimbursement of its denied claims and prohibiting recoupment of overpayments. (Id. at ¶¶ 65, 69.) Alternatively, Plaintiff seeks an order requiring the provision of an administrative appeal remedy for its denied claims. (Id. at ¶ 66. But cf. Answer at ¶¶ 64-70.)

ARGUMENT

I. THERE IS NO SUBJECT MATTER JURISDICTION OVER THIS ACTION

"It is axiomatic that '[a] federal court's subject matter jurisdiction, constitutionally limited by Article III, extends only so far as Congress provides by statute.'" Three Lower Counties Comm. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs., 517 F. Supp. 2d 431, 434 (D.D.C. 2007) (citation omitted). Moreover, "'the plaintiff[] bear[s] the burden of proving by a preponderance of the evidence that the Court has subject matter jurisdiction.'" Carney Hosp. Transitional Care Unit v. Leavitt, 549 F. Supp. 2d 93, 95 (D.D.C. 2008) (citations omitted). In considering the Secretary's instant motion to dismiss for lack of subject matter jurisdiction, the Court should "construe plaintiff's complaint in plaintiff's favor, accepting all inferences that can be derived from the facts alleged." Id. (citation omitted). However, "the court is not limited to the allegations contained in the complaint." Atlantic Urological Assocs., P.A. v. Leavitt, 549 F. Supp. 2d 20, 26 (D.D.C. 2008) (citation omitted). "Instead, to determine

whether it has jurisdiction over the claim, the court may consider materials outside the pleadings." Id. (citation omitted).

A. Federal Question Jurisdiction Is Expressly Precluded by the Medicare Statute, 42 U.S.C. §§ 405(h) and 1395ii, and by Plaintiff's Failure to Exhaust Available Administrative Appeals Remedies

1. Plaintiff alleges subject matter jurisdiction solely under the federal question statute, 28 U.S.C. § 1331. (Compl. at ¶ 4.) However, the Medicare statute, 42 U.S.C. §§ 405(h) and 1395ii, expressly bars federal question jurisdiction, and requires Plaintiff to exhaust available administrative appeals remedies before a final decision of the Secretary can be subject to judicial review under the Medicare statute's exclusive grant of subject matter jurisdiction, 42 U.S.C. §§ 405(g), 1395ff. But there is no allegation in the Complaint that Plaintiff has even filed an administrative appeal of the matters at issue, much less that it has obtained the hearing and final decision of the Secretary required for judicial review under the Medicare statute.

Section 405(h), which is incorporated into the Medicare statute by § 1395ii, provides:

> The findings and decisions of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or government agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28, United States Code, to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). The Medicare statute and regulations afford dissatisfied program beneficiaries, and any assignee of the individual's Part A or Part B benefit claim or the person's appeal rights, several levels of administrative review and, potentially, judicial review. 42 U.S.C. §§ 405(g), 1395ff; 42 C.F.R. Part 405, Subpart I. Plaintiff does not allege that it has made any effort to file any administrative appeals of, or obtained a hearing on, any of the matters raised in

the Complaint, including the alleged denial of $741,442 in reimbursement owing for its 1,714 Part B benefit claims and other monetary relief, and the allegedly unlawful actions taken in the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article. (See Compl. at ¶¶ 45, 64, 65, 67-69.) Similarly, Plaintiff nowhere alleges having obtained the "Secretary's final decision after such hearing" on the matters at issue, which is a requirement for subject matter jurisdiction under the Medicare statute, 42 U.S.C. §§ 405(g), 1395ff. (See pp. 24-30, infra (detailing Plaintiff's failure to satisfy the statutorily imposed exhaustion requirement, and why requiring exhaustion would, in any event, further the interests of administrative finality and judicial economy).

2. Beyond Plaintiff's complete failure to satisfy the prerequisites of subject matter jurisdiction under the Medicare statute, 42 U.S.C. §§ 405(h) and 1395ii expressly foreclose Plaintiff's invocation of federal question jurisdiction as a "fallback argument." Your Home Visiting Nurse Servs., Inc. v. Shalala, 525 U.S. 449, 456 (1999) (§ 405(h) bars § 1331 jurisdiction over a Medicare fiscal intermediary's denial of a provider's request for reopening, even though the reopening denial is also not reviewable under the Medicare statute or the federal mandamus statute). Section 405(h) specifically applies to "any claim arising under" the Medicare statute. As the Supreme Court has held repeatedly, a "claim 'arises under' the Medicare Act within the meaning of this provision . . . [if] 'both the standing and the substantive basis for the presentation' of the claim are the Medicare Act." Id. (quoting Heckler v. Ringer, 466 U.S. 602, 615 (1984)).

Here, Plaintiff's "standing" is clearly predicated on the Medicare statute, for it seeks an order requiring $741,442 in reimbursement for 1,714 denied claims and prohibiting recoupment

of overpayments. (Compl. at ¶¶ 65, 69.) Furthermore, Plaintiff seeks declaratory and injunctive relief as to the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article, and reinstatement of the status quo ante. (Id. at ¶¶ 64, 67, 68.) Plaintiff's standing springs from the Medicare statute inasmuch as entry of the declaratory and injunctive relief sought in the Complaint may leave "only essentially ministerial details . . . before [Plaintiff] would receive reimbursement." Ringer, 466 U.S. at 615.

Moreover, the Medicare statute plainly supplies "'the substantive basis for the presentation' of the claim[s]" at issue. Your Home Visiting Nurse Servs., 525 U.S. at 456 (citation omitted). As explained above, Medicare Part B allows coverage of "medical and other health services," which includes medical supplies. 42 U.S.C. §§ 1395k(a)(1), 1395m(j)(5), 1395x(s)(1), (2)(A), (6), (8), & (9). Certain surgical dressings are among the medical supplies that potentially qualify for Part B coverage. Id. §§ 1395m(j)(5)(D), 1395x(s)(5); 42 C.F.R. § 410.36(a)(1). The non-bordered composite dressings that Plaintiff has supplied to Medicare beneficiaries are surgical dressings that may qualify for Medicare coverage. (See Compl. at ¶¶ 7, 10, 17, 27.) Indeed, the DME contractors' September 2006 Bulletin Article is entitled "Surgical Dressings - Revised Coding Guidelines." (Exhibit A at 1.)

3. Perhaps Plaintiff will respond that its claims arise under the Administrative Procedure Act ("APA") because it is challenging the "procedures" by which the DME contractors revised the definition of "composite dressing" and determined that the HCPCS Level II codes for non-bordered composite dressings are no longer valid for Medicare claims submission. (See Compl. at ¶¶ 26, 28.) The Supreme Court has held, however, that § 405(h)'s bar of federal question jurisdiction is "sweeping and direct," Weinberger v. Salfi, 422 U.S. 749,

757 (1975), and encompasses "all 'claims arising under the' Medicare Act." Ringer, 466 U.S. at 615 (citation omitted). Thus, as this Circuit concluded, under the "Salfi-Ringer line" of precedent, § 405(h) requires that every aspect of any "claim arising under" the Medicare statute - - whether constitutional, APA, substantive, or procedural - - must be "fed through the administrative-judicial system as parts of disputes over actual amounts" of payment. Nat'l Kidney Patients Ass'n v. Sullivan, 958 F.2d 1127, 1130, 1134 (D.C. Cir. 1992).

Indeed, in the Supreme Court's most recent, comprehensive review of the Salfi-Ringer line of authority, the Court explained:

> Those cases themselves foreclose distinctions based upon the "potential future" versus the "actual present" nature of the claim, the "general legal" versus the "fact specific" nature of the challenge, the "collateral" versus "noncollateral" nature of the issues, or the "declaratory" versus "injunctive" nature of the relief sought.

Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 14 (2000). The Court also rejected "a distinction that limits the scope of § 405(h) to claims for monetary benefits" as distinct from claims that "dispute agency policy determinations, or . . . involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions." Id. Thus, the Court concluded that the Medicare statute's comprehensive remedial scheme "demands the 'channeling' of virtually all legal attacks" on Medicare matters "through the agency" before they can be heard in federal court under the statute's own grant of subject matter jurisdiction over a final decision of the Secretary. Id. at 13.

There is no question that Plaintiff seeks Part B reimbursement. Indeed, the supplier seeks payment of a sum certain for 1,714 benefit claims plus an order prohibiting recoupment of overpayments on other claims. (Compl. at ¶¶ 65, 69.) Besides its monetary claims, Plaintiff also

challenges the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article, and the supplier seeks reinstatement of the status quo ante. (Id. at ¶¶ 64, 67, 68.) But regardless of whether Plaintiff's challenge to the DME contractors' actions is deemed "procedural" or assigned some other label, the supplier's allegations about the DME contractors' actions are "inextricably intertwined" with its many Part B benefit claims, and thus § 405(h) bars federal question jurisdiction and requires Plaintiff to exhaust administrative appeals remedies on all aspects of its "claims arising under" the Medicare statute. Ringer, 466 U.S. at 614.

B. Plaintiff's Claims Do Not Fall Within the Ambit of the Limited Exception, Recognized by the Supreme Court, to § 405(h)'s Jurisdictional Bar

1. The Supreme Court has recognized one narrow exception to § 405(h)'s prohibition of federal question jurisdiction for disputes pertaining to the Medicare program. But that limited exception clearly has no bearing on Plaintiff's allegations herein.

In Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667, 668 (1986), an association of physicians brought statutory and constitutional challenges to a Medicare regulation setting forth the "methods" for determining the amount of Part B payment for various physician services. At that juncture, the Medicare statute provided for only limited carrier review of Part B benefit claims, and the Supreme Court had previously ruled that the statute precluded judicial review of the "amount of Part B awards." United States v. Erika, Inc., 456 U.S. 201, 208 (1982). In Michigan Academy, 476 U.S. at 676, 681, the Supreme Court held that Congress did preclude judicial "review of the method by which Part B awards are computed," whereas allowing federal question jurisdiction would ensure a judicial forum for colorable constitutional claims.[2/]

[2/] Four months after the Michigan Academy decision, Congress amended the Medicare statute to provide for full administrative and judicial review of all aspects of Part B benefit

In Illinois Council, the Supreme Court limited the exception to § 405(h) that was countenanced in the Michigan Academy decision. The Court "read Michigan Academy as holding that § 1395ii does not apply § 405(h) [only] where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." Illinois Council, 529 U.S. at 19. The Court emphasized, however, that the scope of the exception to § 405(h)'s jurisdictional preclusion is very limited:

> [W]e do not hold that an individual party could circumvent § 1395ii's channeling requirement simply because that party shows that postponement would mean added inconvenience or cost in an isolated, particular case. Rather, the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what appears to be simply a channeling requirement into complete preclusion of judicial review.

Id. at 22-23 (citation omitted).

2. Plaintiff's claims certainly do not fall within the limited exception to § 405(h)'s jurisdictional bar that was recognized in Illinois Council. First, as a Medicare enrolled supplier of surgical dressings, there is no question that Plaintiff is the kind of entity that can make ready use of the Medicare statute's exclusive system of administrative and judicial review. See 42 U.S.C. § 1395ff(a)(1); 42 C.F.R. § 405.920. Indeed, Plaintiff alleges that the ALJs have already adjudicated approximately 38,000 of its previously denied Part B reimbursement claims and reversed about 98% of the claim denials. (Compl. at ¶ 22.)

---

claims. Nat'l Kidney Patients Ass'n, 958 F.2d at 1132. Given the intervening statutory amendments enabling full administrative and judicial review of the amount, and the methods for determining the amount, of Part B claims, this Circuit and others have concluded that the Michigan Academy rationale for § 1331 jurisdiction has no continuing applicability to Part B claims. Id. at 1134. Accord Am. Acad. of Dermatology v. HHS, 118 F.3d 1495, 1500 (11th Cir. 1997); Farkas v. Blue Cross & Blue Shield, 24 F.3d 853, 860 (6th Cir. 1994); Abbey v. Sullivan, 978 F.2d 37, 41-43 (2nd Cir. 1992).

Second, Plaintiff's claims are plainly garden variety Part B benefit claims, and, as such, the Medicare statute expressly provides for administrative and judicial review of such claims. 42 U.S.C. § 1395ff(a)(1)(B) (an "initial determination of the amount of benefits available . . . under such parts" is subject to administrative and judicial review). See also 42 C.F.R. § 405.920(b) (same). The gravamen of the Complaint is Plaintiff's request for an order seeking "denied reimbursement totaling $741,442" on 1,714 claims for the period from October 1, 2006 through October 31, 2007, and prohibiting recoupment of overpayments. (Compl. at ¶¶ 45, 65, 69.) The statute unquestionably provides for administrative and judicial review of such claims, which "at bottom [raise] a claim that they should be paid" for specific medical supplies. Ringer, 466 U.S. at 614.

Third, although Plaintiff also challenges the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article, which revised the definition of "composite dressing" and determined that the HCPCS Level II codes for non-bordered composite dressings were invalid for Medicare claims submission, (Compl. at ¶¶ 64, 67, 68), there is no question that Plaintiff's challenge to the DME contractors' actions can be raised as part and parcel of their appeals seeking Part B reimbursement for medical supplies. The statute provides that, in addition to appeals of the "amount of benefits available," 42 U.S.C. § 1395ff(a)(1)(B), full administrative and judicial review is available as to "[a]ny other initial determination with respect to a claim for benefits under such parts, including an initial determination . . . that payment may not be made." Id. § 1395ff(a)(1)(C). See also 42 C.F.R. § 405.924(b)(12) (an appealable initial determination includes "[a]ny other issues having a present or potential effect on the amount of benefits to be paid under Part A or Part B"). Given that Plaintiff seeks "payment for some medical procedure"

and "challenges the lawfulness of th[e] denial" of its reimbursement claims, federal question jurisdiction is "plainly" barred, "irrespective of whether [it] challenges the agency's denial on evidentiary, rule-related, statutory, constitutional, or other legal grounds." Illinois Council, 529 U.S. at 10. Accord Ringer, 466 U.S. at 615, 621; Salfi, 442 U.S. at 760-61.

This Circuit's decision in National Kidney Patients Association v. Sullivan, 958 F.2d 1127 (D.C. Cir. 1992) is particularly instructive here. The plaintiffs, a supplier of home dialysis equipment and supplies, ten dialysis patients, and a patients' group, complained that the Secretary's reduction in the rate of Part B reimbursement violated APA notice and comment rulemaking requirements and was arbitrary and capricious under the APA. Id. at 1129. The district court asserted federal question jurisdiction, and granted a preliminary injunction prohibiting the Secretary from recouping $15 million in overpayments. Id. at 1127. (Cf. Compl. at ¶¶ 4, 49-69.) The Court of Appeals ruled that § 405(h) barred § 1331 jurisdiction over plaintiffs' claims regardless of whether plaintiffs were deemed to be challenging the "amount" of Part B payment or the "methods" by which such payment amounts are determined. Id. at 1134. Based on Congress's extension of full administrative and judicial review to all aspects of Part B claims, following the Supreme Court's Michigan Academy decision, the Circuit held that, under the "Salfi-Ringer line" of precedent, § 405(h) requires that "methodology disputes . . . are fed through the administrative-judicial system as parts of disputes over actual amounts" of Part B payment. Id. at 1129, 1133-34. Thus, under the settled precedent of the Supreme Court and this Circuit, § 405(h) limits review of all aspects of Plaintiff's Part B claims, including its APA challenge to the DME contractor's actions, to the exclusive, multi-tiered administrative and judicial review process established by Congress in 42 U.S.C. § 1395ff.

3. Plaintiff may respond that the agency's disposition of the supplier's Part B claims, submitted following the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article, forecloses resort to the administrative appeals process. Yet, in actuality, the steps necessary for Plaintiff to obtain an initial determination, which would allow for appeal of all its claims, are straightforward.

As described previously, some of Plaintiff's claims under HCPCS codes A6200, A6201, and A6202 were processed and paid by the DME MACs for Jurisdiction A and Jurisdiction D. (Compl. at ¶ 46; Answer at ¶ 46.) However, inasmuch as the DME contractors determined, in the September 2006 Bulletin Article and March 2007 Policy Article, that HCPCS codes A6200, A6201, and A6202 were invalid for purposes of Medicare claims submission, the Secretary may decide eventually to recover overpayments made under those three codes. See generally 42 U.S.C. § 1395ddd(f). Each payment to the supplier was made through an initial determination. 42 C.F.R. § 405.920(b). However, each initial determination is subject to "reopening," which is "a remedial action taken to change a final determination or decision that resulted in either an overpayment or underpayment." Id. § 405.980(a)(1). See also 42 U.S.C. § 1395ff(b)(1)(G) (authorizing the reopening and revision of initial determinations under the Secretary's regulatory guidelines). In turn, if one of the initial determinations providing payment to Plaintiff were reopened, any recovery of an overpayment would be made through a "revised determination," and revised determinations are subject to the same administrative and judicial review process as applies to initial determinations. 42 C.F.R. §§ 405.982(a), 405.984. Thus, if the Secretary were to recover overpayments made on Plaintiff's claims under HCPCS codes A6200, A6201, and A6202, there is no question that the full panoply of statutory appeal rights would be available on

the revised determinations springing from the reopening of the initial determinations that produced the original overpayments.

4. The other two DME MACs, for Jurisdiction B and Jurisdiction C, rejected some of Plaintiff's claims, under HCPCS codes A6200, A6201, and A6202, as invalidly coded claims under the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article. (Compl. at ¶ 46; Answer at ¶ 46.) The regulations provide that invalid claim submissions that are rejected by the Medicare contractor and returned to the provider or supplier are not appealable initial determinations. 42 C.F.R. § 405.926(s). Assuming that this regulation applies to those of Plaintiff's claims that were rejected as improperly coded, that would hardly establish the applicability of the limited exception to § 405(h)'s bar of federal question jurisdiction that was recognized in the Illinois Council and Michigan Academy decisions. Put simply, Plaintiff could have submitted claims under other HCPCS codes - - codes that are still valid for purposes of Medicare claims submission - - and then appealed the Medicare contractor's initial determinations on reimbursement claims submitted under such alternative HCPCS codes.

As described previously, the very September 2006 Bulletin Article that is challenged by Plaintiff includes express instructions for the use of alternative HCPCS Level II codes. Specifically, the DME contractors' September 2006 Bulletin Article provides that non-bordered "[d]ressings previously coded as A6200, A6201, and A6202 will be coded as specialty absorptive dressings without adhesive border - - A6251, A6252, and A6253, respectively." (Exhibit A at 2.)[9] If Plaintiff were to submit an appropriate claim under one of the alternative HCPCS Level II

[9] In characterizing the September 2006 Bulletin Article, Plaintiff fails to mention the DME contractors' specific instructions for the use of three alternative HCPCS Level II codes. (See Compl. at ¶ 26.)

codes identified in the September 2006 Bulletin Article, the Medicare contractor would issue an initial determination addressing whether the specific non-bordered dressing was "covered or otherwise reimbursable" and "[d]etermin[ing] any amounts payable and mak[ing] payment accordingly." 42 C.F.R. § 405.920(a), (b). In turn, if Plaintiff were dissatisfied with some aspect of the initial determination, the statute would authorize several levels of administrative review and, potentially, judicial review. 42 U.S.C. § 1395ff. See also 42 C.F.R. Part 405, Subpart I. More specifically, in appealing the initial determination regarding an appropriate claim under one of the alternative HCPCS Level II codes identified in the September 2006 Bulletin Article, the supplier would be free to challenge the DME contractors' revision of the definition of "composite dressing" (now requiring an adhesive border) and their determination that HCPCS Level II codes A6200, A6201, and A6202 are no longer valid for purposes of Medicare claims submission. Since the complained of actions by the DME contractors "hav[e] a present or potential effect on the amount of benefits to be paid under Part A or Part B," 42 C.F.R. § 405.924(b)(12), Plaintiff can challenge the DME contractors' actions in an appeal of an initial determination springing from a Part B claim submitted under one of the alternative HCPCS Level II codes identified in the September 2006 Bulletin Article.

Plaintiff may complain that, at least for some of the surgical dressings furnished already, it would be "too late" to submit Part B reimbursement claims under one of the alternative HCPCS Level II codes identified in the September 2006 Bulletin Article. While there are time limits for the filing of claims, they are generous and Plaintiff may be able to submit claims under the alternative HCPCS codes for many items already furnished to Medicare beneficiaries. See 42 C.F.R. § 424.44. At a minimum, Plaintiff faces no impediment to the submission of claims

under the alternative HCPCS codes for items supplied at a future date.

In any event, to the extent that Plaintiff may have missed the deadline for submitting certain claims under the alternative HCPCS codes, that hardly qualifies it for the limited exception to § 405(h)'s bar of federal question jurisdiction. Nothing in the Supreme Court's decisions in Illinois Council and Michigan Academy suggests that a plaintiff can evade § 405(h)'s jurisdictional preclusion simply because that plaintiff might otherwise be unable to pursue a specific claim through the statutory appeals mechanism established by Congress for claims of the same type. On the contrary, the Supreme Court has made clear that the exception applies only when there would otherwise be "no review at all." Illinois Council, 529 U.S. at 19 (emphasis added). Thus, in Illinois Council itself, the Court held that § 405(h) bars § 1331 jurisdiction over the claims of the sole plaintiff, a trade association, because the non-party members of the association could seek administrative and judicial review of similar claims under the Medicare statute. Id. Similarly, in Ringer, 466 U.S. at 613-16, 620, the Court rejected federal question jurisdiction over Part A benefit claims even though the named plaintiff could not secure administrative and judicial review under 42 U.S.C. § 405(b) & (g) because he could not otherwise afford the disputed surgical procedure, and the other three plaintiffs had already missed the deadlines for appeal of their claims denials. And in Your Home Visiting Nurse Services, 525 U.S. at 451, 455, the Court rejected § 1331 jurisdiction over a Part A fiscal intermediary's reopening denial because "Medicare providers already have the right under [42 U.S.C.] § 1395oo(a)(3) to appeal an intermediary's determination to the [Provider Reimbursement Review] Board," and "[t]he Board's decision is subject to judicial review . . . [under] § 1395oo(f)," leaving it of no consequence that the plaintiff had previously failed to file a timely

appeal to the Board of the underlying reimbursement issue.[7]

Clearly, then, the exception to § 405(h)'s bar of federal question jurisdiction applies only if the Medicare statute includes no mechanism through which an appropriate party, exercising due diligence, can secure administrative and judicial review of the type of claim in question. Plaintiff's failure to follow the DME contractors' express instruction, to submit claims under alternative HCPCS codes, may explain why the supplier has not received appealable "initial determinations" on the matters raised in the Complaint. Regardless, allowing Plaintiff to evade § 405(h)'s bar of federal question jurisdiction would improperly reward its failure to take the straightforward steps necessary to obtain the initial determinations that would allow entry into the Medicare statute's exclusive mechanism for administrative and judicial review of all aspects of its "claims arising under" the statute.

C. Plaintiff Has Not Exhausted Administrative Remedies, Which Is a Prerequisite of Judicial Review Under the Exclusive Provisions of 42 U.S.C. §§ 405(g), 1395ff

1. As shown previously, Plaintiff's Complaint raises only "claims arising under" the Medicare statute, which must channeled through 42 U.S.C. § 1395ff(b), the dedicated administrative and judicial review regime for all aspects of Part B benefit claims. This exclusive

---

[7] See also Am. Chiropractic Ass'n, Inc. v. Leavitt, 431 F.3d 812, 815 (D.C. Cir. 2005) (§ 405(h) precludes federal question jurisdiction over claims of the sole plaintiff, an association of chiropractors, even though it would take non-party individual chiropractors to pursue the same statutory challenge through the exclusive Medicare administrative and judicial review mechanism); Nat'l Athletic Trainers' Ass'n, Inc. v. U.S. Dep't of Health & Human Servs., 455 F.3d 500, 507-08 (5th Cir. 2006) (§ 405(h) bars § 1331 jurisdiction over claims of association of athletic trainers, although non-party physicians would need to pursue the same regulatory challenge through the Medicare appeals regime); St. Francis Med. Ctr. v. Shalala, 32 F.2d 805, 808-14 (3rd Cir. 1994) (§ 405(h) bars § 1331 jurisdiction even though Part A provider could not meet the amount in controversy requirement for administrative and judicial review under § 1395oo); Westchester Mgt. Corp. v. DHHS, 948 F.2d 279, 281-83 (6th Cir. 1991) (same).

grant of subject matter jurisdiction provides:

> [A]ny individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and . . . a hearing thereon by the Secretary to the same extent as is provided in [42 U.S.C. §] 405(b) and, . . . to judicial review of the Secretary's final decision after such hearing as is provided in [§] 405(g).

42 U.S.C. § 1395ff(b)(1)(A). The referenced "reconsideration" must be provided by a "qualified independent contractor" ("QIC"). 42 U.S.C. § 1395ff(b)(1)(A) & (c); 42 C.F.R. § 405.960. Next, an ALJ must conduct any hearing "as provided in [42 U.S.C. §] 405(b)," 42 U.S.C. § 1395ff(b)(1)(A), (E) & (d)(1); 42 C.F.R. § 405.1002, and the ALJ's decision may be reviewed by the Medicare Appeals Council of the Departmental Appeals Board, 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100. Thus, only the final decision of the ALJ or the Medicare Appeals Council, as applicable, constitutes "the Secretary's final decision after such hearing" that is subject to judicial review "as provided in [42 U.S.C. §] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A), (E); 42 C.F.R. § 405.1136.

Plaintiff nowhere alleges, however, that any aspect of its claims, including its challenge to the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article and its demand for $741,442 and other monetary relief, (see Compl. at ¶¶ 45, 64, 65, 67-69), were ever raised with a QIC, an ALJ, or the Medicare Appeals Council. By the same token, there is no allegation in the Complaint that Plaintiff ever obtained a reconsideration by a QIC, an ALJ hearing, or a final post-hearing decision by an ALJ or the Medicare Appeals Council. Thus, Plaintiff plainly fails to allege compliance with any of § 1395ff(b)(1)(A)'s exclusive requirements for judicial review, "as is provided in 42 U.S.C. § 405(g)." See, e.g., Three Lower Counties Comm. Health Servs., 517 F. Supp. 2d at 435 (§ 405(g) jurisdiction "is permitted only

upon the completion of the administrative process outlined in that statute and regulations").

2. It bears emphasis that the "final decision" requirement in 42 U.S.C. § 405(g) is a "statutorily specified jurisdictional prerequisite," not "simply a codification of the judicially developed doctrine of exhaustion." Salfi, 422 U.S. at 766. Moreover, the exclusive jurisdictional prerequisites of the Medicare statute consist of two requirements: "a nonwaivable requirement that 'a claim for benefits shall have been presented to the Secretary;'" and a final decision or exhaustion requirement, which "a district court cannot merely waive . . . for equitable or other policy reasons." Queen of Angels/Hollywood Presbyterian Med. Ctr. v. Shalala, 65 F.3d 1472, 1482 & n.24 (9th Cir. 1995) (citations omitted). Here, Plaintiff clearly has not satisfied the Medicare statute's requirement for judicial review, for it has not obtained a final decision by the Secretary after an administrative hearing on its claims.

Notably, "the power to determine when finality has occurred ordinarily rests with the Secretary since ultimate responsibility for the integrity of the administrative program is his." Mathews v. Eldridge, 424 U.S. 319, 330 (1976). Furthermore, given the Secretary's instant motion to dismiss for lack of subject matter jurisdiction, "it cannot be said that the Secretary has in any sense waived further exhaustion" as to any aspect of Plaintiff's challenge to the DME contractors' actions or its demand for a sum certain and other monetary relief. Ringer, 466 U.S. at 618. Cf. Queen of Angels/Hollywood Presbyterian Med. Ctr., 65 F.3d at 1481-83 (upholding Secretary's express waiver of exhaustion).

3. Plaintiff alleges that the DME contractor's actions "culminated in a final decision of the Secretary denying Plaintiff's claims for Medicare reimbursement." (Compl. at ¶1.) But this lone reference to an alleged final agency decision hardly satisfies the statutory requirements

for judicial review imposed by the Medicare statute. Again, the Complaint is devoid of any allegation that Plaintiff requested or obtained, regarding its challenge to the DME contractors' actions or its demand for a sum certain and other monetary relief, a reconsideration by a QIC, an ALJ hearing, or a final post-hearing decision by an ALJ or the Medicare Appeals Council. Thus, the purported "final decision of the Secretary," as alleged in paragraph 1 of the Complaint, cannot satisfy the statutory requirements for judicial review, "as is provided in 42 U.S.C. § 405(g)." 42 U.S.C. § 1395ff(b)(1)(A).

On the contrary, Plaintiff's insupportable reference to a "final decision" in paragraph 1 of the Complaint is plainly inconsistent with the rest of the Complaint. The fulcrum of the statutory administrative and judicial review mechanism is the requirement of an initial determination on a benefit claim. 42 U.S.C. § 1395ff(b)(1)(A).[8] But Plaintiff nowhere alleges that it received or appealed any initial determinations on the matters at issue. For the claims that were processed and paid, despite the DME contractors' September 2006 Bulletin Article and March 2007 Policy Article, (see Compl. at ¶ 46; Answer at ¶ 46), Plaintiff had no reason to appeal those initial determinations, and, in any event, no such appeal is alleged in the Complaint. As for the claims that were rejected as invalidly coded, Plaintiff alleges that no administrative appeals remedies are available for the claims rejected as invalidly coded. (Id.) See also 42 C.F.R. § 405.926(s). Therefore, since Plaintiff has not alleged receipt of even one bonafide "Secretary's final decision after such hearing," there is no basis for judicial review, "as is provided in 42 U.S.C. § 405(g)," of any aspect of the supplier's challenge to the DME contractors' actions or its demands for a

[8] Plaintiff's informal letters and telephone calls to CMS and the DME contractors, (see Compl. at ¶¶ 42-44), cannot substitute for compliance with the administrative appeals system. Three Lower Counties Comm. Health Servs., 517 F. Supp. 2d at 435 (collecting cases).

sum certain and other monetary relief. 42 U.S.C. § 1395ff(b)(1)(A).

D. Requiring Plaintiff to Exhaust Administrative Appeals Remedies on Its Claims Will Further the Interests of Administrative Finality and Judicial Economy

1. As noted, the "final decision" requirement in 42 U.S.C. §§ 405(g), 1395ff(b)(1) is a "statutorily specified jurisdictional prerequisite," not "simply a codification of the judicially developed doctrine of exhaustion." Salfi, 422 U.S. at 766. Also, the Secretary has not waived the final decision requirement as to any aspect of Plaintiff's claims. In any event, requiring Plaintiff to exhaust administrative remedies will plainly serve the interests of administrative finality and judicial economy.

As explained by the Supreme Court:

> Exhaustion is generally required as a matter of preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review.

Id. at 765 (citation omitted). These objectives would be fully served by requiring Plaintiff to exhaust available administrative appeals remedies.

As set forth in the September 2006 Bulletin Article, the DME contractors determined that a composite dressing must have a "bacterial barrier," but if a dressing has "no adhesive border, there is no assurance that it will prevent bacterial access to a wound when it is applied." (Exhibit A at 1-2.) Thus, in order to better maintain the integrity of the bacterial barrier, the DME contractors required that composite dressings include an adhesive border; determined that HCPCS codes A6200, A6201, and A6201 were invalid for Medicare claims submission; and instructed that non-bordered dressings be coded as specialty absorptive dressings without

adhesive border under HCPCS codes A6251, A6252, and A6252. (Id. at 2.)

Plaintiff alleges that "[t]here is no medical justification for the change in definition" of "composite dressing." (Compl. at ¶39.) According to Plaintiff, the DME contractors' "reasoning is completely flawed." (Id.) Plaintiff further alleges that "several medical opinions from nationally respected wound care experts" support its criticisms of the DME contractors' reasoning. (Id.)

2. The differences of medical opinion, as expressed by the DME contractors and opposed by Plaintiff and the referenced wound care experts, are precisely the kinds of dispute for which Congress crafted the Medicare statute's exclusive administrative and judicial review mechanism. Thus, in reconsidering an initial determination, the QIC's "panel" must have sufficient medical expertise and knowledge of the Medicare program, which will enable the QIC to review and address the conflicting medical opinions regarding the matters raised in the Complaint. 42 C.F.R. § 405.968(c)(1). If Plaintiff were dissatisfied with the QIC's reconsideration, it could proceed to a full-blown evidentiary hearing before an ALJ who would further assess and address the conflicting medical opinions. Id. at §§ 405.1000, 405.1018, 405.1036. Indeed, Plaintiff alleges that the DME PSC Medical Directors provided similar testimony in many ALJ hearings regarding medical necessity issues. (Compl. at ¶ 23.) As for the conflicting medical opinions presented here, they would be reflected in a final decision by the ALJ or the Medicare Appeals Council, and the final agency decision would be subject to judicial review based on the entire record of the administrative proceedings. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A); 42 C.F.R. §§ 405.1042, 405.1048, 405.1130, 405.1136.

Requiring Plaintiff to abide by the full administrative appeals process would guard

against premature interference with agency processes, and give the agency an opportunity to correct its own errors. Salfi, 422 U.S. at 765. As exemplified by the ALJs' 98% reversal rate on Plaintiff's claims denied for lack of medical necessity, (Compl. at 22), the supplier may well prevail in administrative appeals of claims denied after the disputed actions of the DME contractors, which would obviate the need for judicial review. However, if Plaintiff were dissatisfied with the final decision of the ALJ or the Medicare Appeals Council, as applicable, the agency's experience and expertise would have been brought to bear on Plaintiff's claims, and there would be an adequate administrative record for purposes of judicial review. Salfi, 422 U.S. at 765. Thus, as shown previously, the Medicare statute mandates exhaustion of administrative appeals remedies as a prerequisite of federal court subject matter jurisdiction; but, requiring exhaustion of Plaintiff's claims also would clearly serve the interests of administrative finality and judicial economy.

CONCLUSION

For the forgoing reasons, Defendant's Motion to Dismiss should be granted, and Plaintiff's Complaint and this action should be dismissed for lack of subject matter jurisdiction.

Respectfully submitted,

/s/
JEFFREY A. TAYLOR
United States Attorney
D.C. Bar No. 498610

/s/
CHRISTOPHER B. HARWOOD
Assistant United States Attorney
United States Attorney's Office
for the District of Columbia
555 Fourth Street, N.W.
Washington, DC 20530
(202) 307-0372

/s/
GERARD KEATING
Attorney
U.S. Department of Health and
Human Services
Office of the General Counsel
Room 5309 Cohen Building
330 Independence Ave., S.W.
Washington, D.C. 20201
(202) 619-3377

OF COUNSEL:

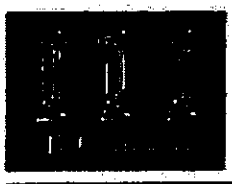
THOMAS R. BARKER
Acting General Counsel
JANICE L. HOFFMAN
Associate General Counsel
MARK D. POLSTON
Deputy Associate General Counsel
for Litigation
ANDREW S.M. TSUI
Attorney

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL TECHNOLOGIES, INC., Plaintiff, v. MICHAEL O. LEAVITT, Secretary, U.S. Department of Health and Human Services, Defendant.	Case No. 1:08-cv-00319 (JDB)

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

EXHIBIT A



TriCenturion
P.O. Box 100282
Columbia, SC 29202-3282

Region A/B DME PSC Bulletin
September 2006

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PHYSICAN/SUPPLIER STAFF. BULLETINS ARE AVAILABLE AT NO COST FROM OUR WEB SITE AT WWW.TRICENTURION.COM

Bul20060901SURG DSG

Surgical Dressings – Revised Coding Guidelines

The revised definitions described in this article are effective for claims with dates of service on or after 10/01/2006.

The SADMERC and DME PSCs have identified a number of surgical dressings in which the size of dressing slightly exceeds 16 square inches – for example, 4 ¼ x 4 ¼. This has resulted in coding these products in a higher priced category. These dressings are not functionally different than 4 x 4 dressings and therefore a decision has been made that they should be coded using the "16 square inches or less" codes. A similar determination has been made for dressings that slightly exceed 48 square inches. If a manufacturer or supplier has a question about the correct coding of a specific product, they should contact the SADMERC for a Coding Verification Review.

Suppliers are reminded that, as stated in the Surgical Dressings LCD, the dressing size must be appropriate for the size of the wound. For wound covers, it would not be appropriate for the pad size to be more than 2 inches greater than the dimension of the wound. This means that a dressing greater than 16 square inches would not be medically necessary if the wound was less than 2 inches (5 cm) across. A dressing greater than 48 square inches would not be medically necessary if the wound was less than 4 inches (10 cm) across.

Small adhesive bandages (e.g., Band-Aid or similar product) are not primarily used for the treatment of wounds addressed in the Surgical Dressings policy. Therefore, these dressings are noncovered under the surgical dressing benefit. If suppliers choose to submit claims for these products, they must be billed with code A9270 (noncovered item or service). If a manufacturer or supplier has a question about the correct coding of a specific product, they should contact the SADMERC for a Coding Verification Review.

Wound cover codes are described as either "without adhesive border" or "with adhesive border". In order to be billed using the "with adhesive border" code, the adhesive border must be present along all sides of the dressing and must be proportionate to the size of the dressing pad and at least ⅛ inch wide.

Codes for composite dressings without adhesive border (A6200, A6201, and A6202) will be invalid for claim submission.. One of the required features of a composite dressing is that it have a bacterial barrier. If a dressing has a waterproof top layer to act as a bacterial barrier but has no

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PHYSICAN/SUPPLIER STAFF. BULLETINS ARE AVAILABLE AT NO COST FROM OUR WEB SITE AT WWW.TRICENTURION.COM

adhesive border, there is no assurance that it will prevent bacterial access to a wound when it is applied. Dressings previously coded as A6200, A6201, and A6202 will be coded as specialty absorptive dressings without adhesive border – A6251, A6252, and A6253, respectively.

Composite dressings with adhesive border (A6203, A6204, and A6205) must have (a) a physical (not chemical) bacterial barrier that is present over the entire dressing pad and extends out into the adhesive border, (b) an absorptive layer other than an alginate or other fiber-gelling dressing, foam, hydrocolloid, or hydrogel, and (c) either a semi-adherent or nonadherent property over the wound site.

A foam dressing (A6209-A6215) is a sterile, nonlinting, absorptive dressing which is made of open cell, medical grade expanded polymer. It has a nonadherent property over the wound site.

The SADMERC has received requests for Coding Verification Review for products with features that go beyond the usual scope of surgical dressings. One example, not all-inclusive, is a product that is intended to provide protection for an indwelling venous catheter. The product is a large wound cover with a slit in the middle and a plastic pouch which covers the dressing and is intended to protect the catheter. For this or other products, the SADMERC/ DME PSC coding determination will be based on the dominant component that falls under the Surgical Dressings benefit category and the intended use of the product. If it is decided that a product meets the definition of a surgical dressing, the coding determination will reflect those features which are appropriate for the management of the wound itself.

These changes will be incorporated in a future revision of the Surgical Dressings medical policy.

AO 440 (Rev. 02/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

CENTRAL DISTRICT OF CALIFORNIA

Gordian Medical, Inc.

Plaintiff

v.

Kathleen Sebelius, Secretary of Department of Health and Human Servi

Defendant

Civil Action No. CV10-3933 CBM (FFMx)

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

KATHLEEN SEBELIUS, Secretary of Department of Health and Human Services, 200 Independence Avenue, SW, Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Mark Kadzielski, Robert M. Dawson, Fulbright & Jaworski L.L.P., 555 S. Flower Street, 41st Floor, Los Angeles, CA 90071

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: May 25, 2010

Signature of Clerk or Deputy Clerk

Central District of California

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4(l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ _____ .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA

CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)

Gordian Medical, Inc.

DEFENDANTS

Kathleen Sebelius, Secretary of Department of Health and Human Services

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)

Robert M. Dawson
FULBRIGHT & JAWORSKI L.L.P.
555 S. Flower Street
41st Floor
Los Angeles, CA 90071
213-892-9200

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☐ Yes ☒ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☒ No ☐ **MONEY DEMANDED IN COMPLAINT: $** _____

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Medicare appeal.

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Act
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Info. Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☒ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpractice
- ☐ 365 Personal Injury-Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus-Alien Detainee
- ☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/Accommodations
- ☐ 444 Welfare
- ☐ 445 American with Disabilities - Employment
- ☐ 446 American with Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence Habeas Corpus
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus/ Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/ PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 USC 7609

CV10-3933 CBM (FFMx)

FOR OFFICE USE ONLY: Case Number: _____

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? [X] No [ ] Yes

If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? [X] No [ ] Yes

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)
- [ ] A. Arise from the same or closely related transactions, happenings, or events; or
- [ ] B. Call for determination of the same or substantially related or similar questions of law and fact; or
- [ ] C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- [ ] D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.

[ ] Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County, California	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.

[X] Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.

Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County, California	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**

Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ **Date** May 25 2010

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program.. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge Consuelo B. Marshall and the assigned discovery Magistrate Judge is Frederick F. Mumm.

The case number on all documents filed with the Court should read as follows:

CV10- 3933 CBM (FFMx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

---

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[X] **Western Division** **312 N. Spring St., Rm. G-8** **Los Angeles, CA 90012**	[ ] **Southern Division** **411 West Fourth St., Rm. 1-053** **Santa Ana, CA 92701-4516**	[ ] **Eastern Division** **3470 Twelfth St., Rm. 134** **Riverside, CA 92501**

Failure to file at the proper location will result in your documents being returned to you.